BRITISH STANDARD

BS EN
591:2001

Instructions for use for in vitro diagnostic instruments for professional use

The European Standard EN 591:2001 has the status of a British Standard

ICS 11.040.55

National foreword

This British Standard is the official English language version of EN 591:2001. It supersedes BS EN 591:1995 which is withdrawn.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 Committee, was published under the authority of the Standards Committee and comes into effect on 15 May 2001

Summary of pages

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EUROPEAN STANDARD

NORME EUROPÉENNE

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EN 591

March 2001

ICS 11.100

Supersedes EN 591:1994

English version

Instructions for use for in vitro diagnostic instruments for professional use

Notices d'utilisation des instruments pour le diagnostic in vitro pour usage professionnel

Gebrauchsanweisungen für Geräte für in-vitro-diagnostische Untersuchungen zum Gebrauch durch Fachpersonal

This European Standard was approved by CEN on 19 January 2001.

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 Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the officia versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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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 September 2001, and conflicting national standards shall be withdrawn at the latest by September 2001.

This European Standard supersedes EN 591:1994.

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 EC Directive(s).

For relationship with EC 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, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

1 Scope

This standard specifies the requirements for the contents of instructions for use for in vitro diagnostic instruments including apparatus, equipment, calibrators and control materials for professional use, hereafter called IVD instruments.

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

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 edition 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
calibrator
substance, material or article intended by its manufacturer to be used to establish the measurement relationships of an in vitro diagnostic medical device
[EN 375]

3.2
control material
substance, material or article intended by its manufacturer to be used to verify the performance characteristics of an in vitro diagnostic medical device
[EN 375]

3.3
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

3.4
internal quality control
operational techniques and activities at the point of use that are used to fulfil requirements for quality of services
[EN 375]

NOTE Internal quality control comprises all steps of activity for production of results from collection of sample and measurement of a measurable quantity to reporting of result of measurement.

3.5
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 [4].

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

3.6
professional use
use by personnel who have received special education and training with regard to procedures utilizing in vitro diagnostic medical devices
[EN 375]

3.7
specimen
biological material which is obtained in order to detect or to measure one or more quantities
[EN 375]

4 Form and presentation of the instructions for use

The wording shall be readily understandable. The following shall be given, where appropriate:

a) overview of operating elements;

b) flow and block diagrams of instrument construction;

c) integration and arrangement of text/illustrations;

d) graphic emphasis of warnings;

e) examples;

f) diagrams of procedural steps;

g) relevant scientific literature.

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 5.23. This information may be supplied in different ways, e. g. as user manual, part of the built-in software of the instrument, audio or video recording or other electronic means.

Instructions for use shall include a table of contents and an index.

Languages shall be used in accordance with the requirements of the country(ies) in which the IVD instrument is distributed.

5.2 Graphical symbols

Any graphical symbols used on the IVD instrument shall be explained in the instructions for use, if no European or International Standards exist to which the symbols used conform.

NOTE Any graphical symbols used on the IVD instrument should be explained and/or the relevant European or International Standards should be given.

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 modules, including, where applicable, software shall be given.

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 shall be given relevant to:

a) any special, unusual risks related to installation, operation, maintenance, transportation, storage or disposal of the IVD instrument;

> NOTE Examples of such risks are those related to handling and disposal of infectious or potentially infectious materials.

b) known interferences;

c) use not recommended by the manufacturer.

5.7 Intended purpose

The intended purpose of the IVD instrument shall be clearly stated.

5.8 Installation

5.8.1 General

Instructions for setting up the IVD instrument shall be given when the installation can be carried out by the user.

> NOTE These instructions are not necessary when the installation is carried out exclusively by personnel from the manufacturer or a service organization.

5.8.2 Action upon delivery

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

Information shall be provided on the following:

a) installation site requirements;

b) technical prerequisites, e. g. load bearing capacity.

5.8.4 Bringing into operation

Information shall be provided on the following:

a) setting up;

b) introduction, brief description;

c) checks for proper installation.

5.9 Theory

Basic theory of the instrument operation shall be given.

If any particular training of the user is required this shall be indicated.

5.10 Functions

Information shall be provided on the following:

a) description, purpose;

b) principles of working;

c) operation;

d) specifications;

e) automatic checks on the system;

f) specific performance checks.

5.11 Performance and limitations of use

Information shall be provided on the following:

a) general statements;

b) performance characteristics of the IVD instrument, e. g. precision, throughput.

5.12 Preparation prior to operation

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, pre-treatment and, if necessary, storage conditions;

d) instrument checks for correct and safe operation;

e) adjustment.

5.13 Operating procedure

A detailed description of the procedure to be followed which can be clearly understood by the user of the IVD instrument shall be provided. This shall include the principle of the method as well as all phases of the operation from start up to reading of result(s).

5.14 Presentation of analytical data

A description of the mathematical approach used for calculation of the analytical result shall be given. This shall be easily understandable for users of the IVD instrument and shall help them to interpret the analytical results.

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

5.15 Special functions

Information shall be provided on special functions where applicable.

EXAMPLES:

special function and performance checks;

specimen identification;

data output, notation, storage, security and transfer;

special settings other than the normal mode of operation;

interface protocol.

5.16 Shut-down procedure

Information shall be provided on the following:

a) placing on stand-by;

b) switching off;

c) taking out of operation.

5.17 Emergency procedure

Operating procedure for emergency specimens shall be provided where applicable.

5.18 Internal quality control

Information shall be provided on the following:

a) checking the function of the IVD instrument;

b) verification of results;

c) internal quality control of the entire in vitro diagnostic system.

5.19 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).

5.20 Maintenance

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;

f) servicing;

g) list of recommended spare parts.

5.21 Trouble-shooting

Information shall be provided on the following:

a) messages, error signals;

b) establishing cause(s) of error(s);

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.

5.22 Technical specifications

Information shall be supplied on the following:

a) if appropriate, limitations on physical environment required for function according to manufacturer's specifications, e. g. humidity, temperature, vibration, magnetic fields, external electrical influences, electrostatic discharge, pressure, acceleration, thermal ignition sources;

b) dimensions, mass;

c) basic settings made by the manufacturer;

d) physical data, e. g. voltage, water pressure;

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

f) if appropriate, electromagnetic emission and immunity.

5.23 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 6.8.

6.2 Brief operating instructions

Brief operating instructions shall be provided.

NOTE This can be provided in the form of a card to be attached to the instrument.

6.3 List of uses and applications

Information on uses and applications shall be provided.

6.4 Warranty limitations

A statement of specific warranty limitations shall be provided.

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

6.5 Ordering information

Information shall be provided on the following:

a) list of spare parts and consumables;

b) relevant addresses, e. g. source of appropriate IVD reagents.

6.6 Possibilities of extension

Information shall be provided on the following:

a) interface description;

b) modules;

c) software;

d) nature and function of connectors.

6.7 Assistance

Information shall be provided on the following:

a) training;

b) service request protocol;

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

d) logbook;

e) user updatable software.

6.8 Supplementary theoretical information

Supplementary theoretical information shall be given.

Annex ZA
(informative)

Relationship of this document with EC 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 EC Directive 98/79/EC.

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.

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

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.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 (r), B.8.7 (s)	
5.7	B.8.5	
5.8	B.8.7 (n)	
5.9	B.8.7 (h)	
5.11	B.8.7 (d), B.8.7 (h)	
5.12	B.8.7 (e), B.8.7 (f), B.8.7 (m), B.8.7 (n), B.8.7 (o)	
5.13	B.8.4 (i), B.8.7 (a), B.8.7 (g), B.8.7 (h)	
5.14	B.8.7 (i)	
5.18	B.8.7 (k)	
5.19	B.8.7 (n)	
5.20	B.8.7 (n), B.8.7 (p), B.8.7 (q)	
5.21	B.8.7 (j)	
5.22	B.4.2, B.8.7 (r)	
5.23	B.8.7 (u)	
6.6	B.8.7 (m)	
6.7	B.8.7 (h)	

Bibliography

[1] EN 375, *Information supplied by the manufacturer with in vitro diagnostic reagents for professional use*.

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

[3] EN 61010-1, *Safety requirements for electrical equipment for measurement, control and laboratory use — Part 1: General requirements (IEC 1010-1:1990 + A1:1992, modified).*

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

[5] ISO/IEC Guide 2, *Standardization and related activities — General vocabulary.*

[6] *International Vocabulary of Basic and General Terms in Metrology*, 2nd edition, Geneva, ISO, 1993.

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