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In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) —

Part 5: *In vitro* diagnostic instruments for self-testing

Dispositifs médicaux de diagnostic in vitro — *Informations fournies par le fabricant (étiquetage) —*

Partie 5: Instruments de diagnostic in vitro *pour auto-tests*

Reference number
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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 18113-5 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and* in vitro *diagnostic test systems*.

ISO 18113 consists of the following parts, under the general title In vitro *diagnostic medical devices — Information supplied by the manufacturer (labelling)*:

— *Part 1: Terms, definitions and general requirements*

— *Part 2:* In vitro *diagnostic reagents for professional use*

— *Part 3*: In vitro *diagnostic instruments for professional use*

— *Part 4:* In vitro *diagnostic reagents for self-testing*

— *Part 5:* In vitro *diagnostic instruments for self-testing*

Introduction

Manufacturers of *in vitro* diagnostic (IVD) instruments for self-testing supply users with information to enable the safe use and expected performance of their devices. Adequate instructions for use are essential for the safe and proper operation of IVD instruments. The type and level of detail varies according to the intended uses and country-specific regulations.

The Global Harmonization Task Force (GHTF) encourages convergence of the evolution of regulatory systems for medical devices at the global level. Eliminating differences among regulatory jurisdictions could allow patients earlier access to new technologies and treatments. See Reference [7]. This part of ISO 18113 provides a basis for harmonization of labelling requirements for IVD instruments for self-testing.

This part of ISO 18113 is concerned solely with information supplied with IVD instruments and equipment intended for self-testing. It is intended to be used in conjunction with ISO 18113-1, which contains the general requirements for information supplied by the manufacturer and definitions of general labelling concepts.

This part of ISO 18113 is based on EN 592[5]. The text has been modified to conform to Part 2 of the ISO/IEC Directives[4], but the requirements, including those in ISO 18113-1, are substantially equivalent to the original European harmonized standard. This part of ISO 18113 is intended to support the essential labelling requirements of all the GHTF partners, as well as other countries that have enacted or plan to enact labelling regulations for IVD medical devices.

For IVD instruments that are intended to be used as a system with reagents provided by the same manufacturer, this part of ISO 18113 is also intended to be used together with ISO 18113-1 and ISO 18113-4[3].

In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) —

Part 5: *In vitro* diagnostic instruments for self-testing

1 Scope

This part of ISO 18113 specifies requirements for information supplied by the manufacturer of IVD instruments for self-testing.

This part of ISO 18113 also applies to apparatus and equipment intended to be used with IVD instruments for self-testing.

This part of ISO 18113 can also be applied to accessories.

This part of ISO 18113 does not apply to

a) instructions for instrument servicing or repair,

b) IVD reagents, including calibrators and control materials for use in control of the reagent,

c) IVD instruments for professional use.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 18113-1, In vitro *diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements*

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

IEC 61010-2-101, *Safety requirements for electrical equipment for measurement, control and laboratory use — Part 2-101: Particular requirements for* in vitro *diagnostic (IVD) medical equipment*

IEC 61326-2-6, *Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 2-6: Particular requirements* — In vitro *diagnostic (IVD) medical equipment*

IEC 62366, *Medical devices — Application of usability engineering to medical devices*

EN 980, *Symbols for use in the labelling of medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18113-1 apply.

4 Essential requirements

The requirements of ISO 18113-1 apply.

ISO standards for specific IVD medical devices may also contain requirements for information supplied by the manufacturer.

EXAMPLES ISO 15197[1]; ISO 17593, [2].

5 Labels and marking

5.1 General

The requirements of IEC 61010-1, IEC 61010-2-101 and IEC 61326-2-6 concerning labels and markings apply.

For the use of symbols, the requirements of ISO 15223-1 and EN 980 apply.

5.2 Identification of the IVD instrument

5.2.1 IVD instrument name

The name of the IVD instrument shall be given.

When the name does not uniquely identify the IVD instrument, an additional means of identification shall also be given.

EXAMPLES Catalogue number, commodity number.

5.2.2 Serial number

A unique serial number shall be given for IVD instruments.

NOTE All instruments covered by IEC 61010 require serial numbers.

Where serial numbers are not practical for apparatus, equipment or accessories intended to be used with IVD instruments, a batch code may be used instead.

EXAMPLE A primary sample receptacle would be assigned a batch code.

5.2.3 *In vitro* diagnostic use

The *in vitro* diagnostic use of the instrument shall be indicated when required by regulation.

EXAMPLES “For *in vitro* diagnostic use” or graphical symbol: “*in vitro* diagnostic medical device”.

6 Elements of the instructions for use

IVD instruments for self-testing shall be supplied with easy to understand instructions for use.

The instructions for use for IVD instruments for self-testing shall include the following, where appropriate:

a) table of contents;

b) overview of operating elements;

c) flow and block diagrams of instrument configuration;

d) integration and arrangement of text and illustrations;

e) graphic emphasis of warnings;

f) examples of how to use the instrument;

g) diagrams of procedural steps;

h) list of accessories;

i) an index;

j) version control identification and first date of applicability.

NOTE Recommendations for developing user instruction manuals for medical devices used in home health care are found in Reference [8].

If a manufacturer provides a complete system containing reagents and instrument, required information may alternatively be included in the instructions for use for the reagents or in a combined manual for the system.

7 Content of the instructions for use

7.1 Manufacturer

The name and address of the manufacturer shall be given.

NOTE In the European Union, the name and address of the manufacturer's "EC Authorized Representative" is also required if the legal manufacturer is not located within the EU. (See Reference [6].)

7.2 Identification of the IVD instrument

7.2.1 IVD instrument name

The name of the IVD instrument shall be given.

When the name does not uniquely identify the IVD instrument, an additional means of identification shall also be given.

EXAMPLES Catalogue number, commodity number.

7.2.2 Module and software identification

Separate instrument modules and/or software shall be identified by name and, if applicable, version.

7.3 Intended use

The intended use of the IVD instrument shall be described in terminology suitable for a lay person.

The benefits and limitations of the IVD instrument with respect to the intended use shall be described.

Medical use shall be described, where appropriate.

EXAMPLE Self-testing of blood glucose for the management of diabetes mellitus.

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

7.4 Storage and handling

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

7.5 Warnings and precautions

Information relevant to the following shall be given:

a) residual risks related to installation, operation, maintenance, transportation, storage or disposal of the IVD instrument and/or its accessories;

   EXAMPLE Risks related to handling and disposal of infectious or potentially infectious materials.

b) known interferences that present significant risk;

c) electromagnetic compatibility, emission, and immunity, and the requirements of IEC 61326-2-6 apply;

The requirements of IEC 61010-1, IEC 61010-2-101, IEC 62366 and ISO 14971 pertaining to information for safety apply.

NOTE Information that enables users to reduce a risk is called “information for safety”. See ISO 14971.

7.6 Instrument installation

7.6.1 General

Instructions for installation of the IVD instrument shall be given when the installation is intended to be carried out by the user.

These instructions are not necessary when the installation is carried out exclusively by personnel from the manufacturer or its representatives.

Information on available accessories and proper connectivity shall be provided.

EXAMPLE 1 Computer interface, modules, optional software, connectivity hardware.

A statement of specific warranty limitations, or where such warranty information can be obtained, shall be provided.

EXAMPLE 2 Actions by users that invalidate the manufacturer's warranty.

7.6.2 Action upon delivery

Information shall be provided on the following:

a) unpacking;

b) checking delivery for completeness;

c) checking for damage during transport.

7.6.3 Bringing into operation

Information shall be provided on the following:

a) brief description of set-up process including procedural steps;

EXAMPLES Connection to utilities, connection to necessary components.

b) function checks for proper installation.

7.7 Principles of measurement

A short summary of the basic principles of measurement shall be given.

7.8 Performance of the IVD instrument

Information shall be provided on the performance characteristics of the IVD instrument.

7.9 Limitations of use

Information shall be provided on the limitations of use of the IVD instrument.

EXAMPLES Sample viscosity, accessory compatibility, computer connectivity.

7.10 Preparation prior to operation

Information shall be provided on the following, where appropriate:

a) any particular training of the user required;

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

c) ordering information for reagents and consumables;

d) type of primary sample to be used;

e) any special conditions of primary sample collection, and storage conditions;

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

7.11 Operating procedure

A detailed description of the procedure for performing the IVD examination shall be provided.

The procedure should be written using simple terms that can be clearly understood by a lay person. The description should avoid using technical or scientific language as much as possible.

Where it would improve understanding, the operating procedure shall be illustrated with flow diagrams, screen shots and/or pictures.

NOTE Abbreviated operating instructions can be helpful to a lay person.

7.12 Control procedure

Adequate information about a means to verify that the IVD instrument is performing within specifications shall be provided.

EXAMPLES For glucose meters, identification of acceptable control materials, frequency of examination of control materials, actions to be taken when control data are out of established control limits.

7.13 Reading of examination results

Instructions on how to read the result of the IVD examination shall be provided.

Results shall be expressed and presented in a way that can be readily understood by a lay person.

Results shall be expressed and presented in such a way as to avoid misinterpretation by a lay person.

Information shall be provided on factors that may lead to incorrect results, together with appropriate precautions.

7.14 Special functions

Information shall be provided on the following, where appropriate:

a) automatic checks on the system;

b) a procedure by which the user can reasonably verify that the IVD instrument will perform or has performed as intended at the time of use;

c) simple performance checks of the entire system.

7.15 Shut-down procedure

Information shall be provided on the following:

a) placing the IVD instrument on stand-by;

b) switching the IVD instrument off;

c) temporarily taking the IVD instrument out of operation.

7.16 Disposal information

Information shall be provided on the safe disposal of hazardous waste materials, accessories and instruments at their end of life.

EXAMPLES Consumables, used reagents or reagent products, including those mixed with primary samples, instruments, components, accessories, discharged batteries.

Manufacturers should encourage users to contact their healthcare provider regarding local waste disposal requirements.

7.17 Maintenance

Information shall be provided on the following, where appropriate:

a) preventive maintenance to be performed by the user (nature and frequency);

b) instructions for cleaning to be performed by the user (compatible materials, procedure, frequency).

7.18 Troubleshooting

Information shall be provided on the following:

a) interpretation of malfunction messages;

b) determining causes of common malfunctions;

c) malfunctions that can be corrected by the user;

d) actions to be taken in the event that controls are out of range.

7.19 Follow-up action

Advice shall be given on actions to be taken based on the IVD examination results, taking into account the possibility of incorrect results.

The information shall include a statement directing the user not to make any decision of medical relevance without first consulting his or her healthcare provider.

Bibliography

[1] ISO 15197, In vitro *diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus*

[2] ISO 17593, *Clinical laboratory testing and* in vitro *medical devices — Requirements for* in vitro *monitoring systems for self-testing of oral anticoagulant therapy*

[3] ISO 18113-4, In vitro *diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 4:* In vitro *diagnostic reagents for self-testing*

[4] ISO/IEC Directives, *Part 2, Rules for the structure and drafting of International Standards*

[5] EN 592:2002, *Instructions for use for* in vitro *diagnostic instruments for self-testing*

[6] *Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 on* in vitro *diagnostic medical devices*, Official Journal of the European Union L331, 7 December 1998

[7] Global Harmonization Task Force (GHTF), Labelling for Medical Devices, Final Document GHTF/SG1/N43:2005, 3 June 2005

[8] BACKINGER, C.L. and KINGSLEY, P.A. *Write It Right: Recommendations for Developing User Instruction Manuals for Medical Devices Used in Home Health Care*, Rockville, MD, USA, U.S. Food and Drug Administration, Center for Devices and Radiological Health, HHS Pub. FDA 93-4258 (August 1993). Available at: www.fda.gov/cdrh/dsma/897.pdf

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