INTERNATIONAL STANDARD

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

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

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

Partie 3: Instruments de diagnostic in vitro à usage professionnel

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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 18113-3 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 professional use supply users with information to enable the safe use and expected performance of their devices. 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 [5]. This part of ISO 18113 provides a basis for harmonization of labelling requirements for IVD instruments for professional use.

This part of ISO 18113 is concerned solely with information supplied with IVD instruments and equipment intended for professional use. 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 591[3]. The text has been modified to conform to Part 2 of the ISO/IEC Directives[2], 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 or plan to enact labelling regulations for IVD medical devices.

For IVD instruments for professional use 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 18113-2[1].

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

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

1 Scope

This part of ISO 18113 specifies requirements for information supplied by the manufacturer of IVD instruments for professional use.

This part of ISO 18113 also applies to apparatus and equipment intended to be used with IVD instruments for professional use.

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 self-testing.

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.

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 marking 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.

All instruments covered by the IEC 61010 series require serial numbers.

Where serial numbers are not practical for apparatus, equipment or accessories intented 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 The words “for *in vitro* diagnostic use” or graphical symbol: “*in vitro* diagnostic medical device”.

6 Elements of the instructions for use

The instructions for use for professional use instruments 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) references to relevant scientific literature;

j) an index;

k) version control identification and first date of applicability.

A searchable electronic instrument guide may not require a table of contents or an index.

The information provided together with the IVD instrument shall as a minimum cover: pertinent safety, installation and environmental requirements.

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 [4].

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.

EXAMPLE Measurement of analytes in biological primary samples, using reagents and calibrators intended for use with this instrument.

Benefits and limitations of the IVD medical device with respect to the intended use shall be described. Medical use may be described, where appropriate.

7.4 Storage and handling

Instructions relevant to any particular environmental requirements, and 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 of the manufacturer or their representatives.

Information on available accessories including 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 Site preparation prior to installation

Information shall be provided on the following, where appropriate:

a) physical environment required for proper functioning;

EXAMPLES Limits of humidity, temperature, vibration, magnetic fields, external electrical influences, electrostatic discharge, pressure, acceleration, thermal ignition sources, environmental noise, proximity to air conditioning or heating ducts.

b) space requirements and clearance limits;

c) technical prerequisites;

EXAMPLES Load-bearing capacity, appropriate utilities, voltage, water pressure.

d) dimensions, mass;

e) basic settings made by the manufacturer;

f) consumption values;

EXAMPLES Electrical power, water.

g) noise level generated by the instrument (in decibels);

h) electromagnetic compatibility, emission and immunity.

7.6.4 Bringing into operation

Information shall be provided on the following:

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

EXAMPLES Connection to utilities, connection to necessary components.

b) function checks for proper installation.

7.7 Theory of operation

Basic principles of the technology used in instrument operation shall be given.

7.8 Functions

For each specific IVD instrument function, information shall be provided on the following:

a) the subsystems and their purpose;

b) functional specifications for major subsystems.

EXAMPLES A sample pipette delivery volume is within ± 2 % relative volume error from 5 µl to 20 µl; a reagent pipette dispenses within CV 2 % from 50 µl to 200 µl.

7.9 Performance of the IVD instrument

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

EXAMPLES Throughput, carryover, cross-contamination, sample volume, reagent volume, measuring time, measuring temperature, absorbance linearity of photometer, wavelength.

7.10 Limitations of use

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

EXAMPLES Sample viscosity, accessory compatibility, computer connectivity.

7.11 Preparation prior to operation

Information shall be provided on the following, where appropriate:

a) any particular training of the user that is required;

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

EXAMPLES Solutions, diluents, buffers, cups, etc. that are necessary for proper operation.

c) ordering information for reagents and consumables;

d) types of sample containers;

e) types of acceptable primary samples;

EXAMPLES Blood, serum, plasma, urine, spinal fluid.

f) instrument checks for safe and correct operation, including calibration;

g) hardware adjustments, if required.

7.12 Operating procedure

A detailed description of the procedure for performing the IVD examination shall be provided. The procedure shall include all phases of the operation from start-up to reading of results.

NOTE Abbreviated operating instructions, such as on a card to be attached to the instrument, can be helpful to the user.

7.13 Control procedure

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

NOTE Users are responsible for determining the appropriate quality control procedures for their laboratory and for complying with applicable laboratory regulations.

EXAMPLES Identification of acceptable control materials, frequency of examination of control materials.

7.14 Calculation of examination results

The mathematical approach, when examination results are calculated, shall be provided.

NOTE If the user must perform a calculation, an example calculation can aid the user's understanding.

EXAMPLE Calculations of the parameters required to interpret a kinetic assay.

7.15 Special functions

Information on the following shall be provided, where appropriate:

a) special function and specific performance checks;

b) automatic checks on the system;

c) primary sample identification;

d) data output, notation, storage, security and transfer;

e) special settings other than the normal mode of operation;

f) interface protocol.

7.16 Emergency primary samples

A procedure for inserting an emergency primary sample into the routine operation shall be provided, where appropriate.

7.17 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.

7.18 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, instrument, components and accessories.

Manufacturers should encourage users to check with local waste disposal authorities for specific requirements.

7.19 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);

c) guidance on sterilization, decontamination or disinfection to be performed by the user to ensure safe use by the user and prior to a physical intervention by the supplier or service personnel;

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

e) servicing contact information;

f) recommended spare parts and consumables to be replaced by the user.

7.20 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) malfunctions necessitating service calls;

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

Bibliography

[1] ISO 18113-2, In vitro *diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2:* In vitro *diagnostic reagents for professional use*

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

[3] EN 591, *Instructions for use for* in vitro *diagnostic instruments for professional use*

[4] 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

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

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