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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 140, *In vitro diagnostic medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 18113-3:2009), which has been technically revised.

The main changes are as follows:

— Updated text to reflect changes in regulations and provide examples for clarity;

— Added information pertaining to unique device identifier-device identifier (UDI);

— Updated the Bibliography.

A list of all parts in the ISO 18113 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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 International Medical Device Regulators Forum (IMDRF) encourages convergence of the evolution of regulatory systems for medical devices at the global level. Eliminating differences among regulatory jurisdictions can allow patients earlier access to new technologies and treatments. This document provides a basis for harmonization of labelling requirements for IVD instruments for professional use.

This document 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 document is intended to support the essential labelling requirements of all the IMDRF[5] 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 document is also intended to be used together with ISO 18113-1 and ISO 18113-2.

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

Part 3: In vitro diagnostic instruments for professional use

1 Scope

This document specifies requirements for information supplied by the manufacturer of in vitro diagnostic (IVD) instruments intended for professional use.

This document also applies to apparatus and equipment intended to be used with IVD instruments for professional use.

This document can also be applicable to accessories.

This document 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 documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 information to be supplied by the manufacturer — 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 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

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 apply.

When including on the labelling any language regarding the manufacturer's liability in the case of damage or injury resulting from any use or malfunction of the device, the laws or regulations in the jurisdiction of use should be taken into consideration.

The labelling shall not contain any disclaimers related to the safety and performance of the device for its intended purpose that are incompatible with the obligations of the manufacturer to design and manufacture a product that is safe and performs as intended throughout its expected lifetime. The laws and regulations in the jurisdiction of use should be taken into consideration.

5.2 Identification of the IVD instrument

5.2.1 IVD instrument name

The name or trade 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 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

Regulations can require the IVD use of the instrument to be indicated.

EXAMPLES The words "for in vitro diagnostic use" or graphical symbol: "in vitro diagnostic medical device".

NOTE In some countries, authorities having jurisdiction can set local requirements for the content of the intended use statement. For example, in the United States, an indication is given that the device is intended for IVD use.

5.2.4 Unique device identifier (UDI)

It should be taken into consideration that if the IVD instrument is subject to unique identification rules by the regulatory authority, the outer label should provide the UDI including the UDI carrier (Automatic Identification Data Carrier 'AIDC' format), and Human Readable Interpretation (HRI).

When AIDC carriers other than the UDI carrier are part of the product labelling, the UDI carrier shall be readily identifiable.

The UDI shall include both the UDI device identifier (UDI-DI) and the UDI production identifier (UDI-PI); specific exemptions which are provided by regulations should be taken into consideration.

For the IVD instrument, the UDI-PI shall include at least the serial number unless the instrument is managed by batch code, in which case the batch code shall be included.

If there also is a manufacturing date on the label for reasons other than production control purposes, it does not need to be included in the UDI-PI; specific requirements provided by regulations should be taken into consideration.

If there are significant constraints limiting the use of both AIDC and HRI on the label, the AIDC format shall be generally preferred except for environments where HRI is more appropriate to the user.

The UDI carrier shall be readable during normal use, storage conditions, and throughout intended life of the IVD instrument. ISO/IEC 15415 should be referred to for bar code specifications and symbol quality criteria.

The placement of the UDI carrier shall be done in a way that AIDC method can be accessed during normal operation or storage.

The UDI may be placed on a separate label from other required information.

A single finished IVD instrument made up of multiple parts that have to be assembled may have the UDI Carrier only on one part.

Local, national or regional regulations can apply.

NOTE 1 The content, format, and size of the UDI is specified by the accredited UDI issuing agency selected.

NOTE 2 HRI text is not the same as the text that is already placed on the label and is a legible interpretation of the data characters encoded in the UDI Carrier.

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 warning messages of all levels;

f) examples of how to use and maintain 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;

l) symbols glossary;

m) abbreviations of terms;

n) intended use;

o) components and set up;

p) information on software including cybersecurity;

q) operating instructions;

r) cleaning and disinfection instructions;

s) preventative maintenance and troubleshooting;

t) support information.

It is possible that a searchable electronic instrument guide does not require a table of contents or an index.

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

7 Content of the instructions for use

7.1 Manufacturer

The name, registered trade name or registered trademark and address of the manufacturer shall be given. The address indicates a single point at which the manufacturer can be contacted, e.g. street, number, city, postal code and country. A telephone number and/or fax number and/or website address to obtain technical assistance shall be provided.

If an Authorised Representative is acting on behalf of the manufacturer in the country/jurisdiction, whether the regulatory agency having jurisdiction requires the instructions for use to contain the address of the Authorised Representative, should be taken into consideration.

7.2 Identification of the IVD instrument

7.2.1 IVD instrument name

The name or trade name of the IVD instrument shall be given. This brand or trade name should allow its differentiation from other products of the same or similar type.

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/Intended purpose

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.

The intended user shall be described, as appropriate (e.g. near patient and laboratory professional use, healthcare professionals).

7.4 Storage and handling

Instructions relevant to any particular environmental requirements, and handling and/or storage conditions shall be given. Use of non-specific temperature or humidity indications that are open to interpretation shall be avoided. Where appropriate, any protective measures and interferences shall be listed; a list of approved compatible substances which can be used for cleaning shall be provided.

7.5 Warnings and precautions and/or measures to be taken and limitations of use regarding the instrument

Information shall be given in the form of warnings, precautions and/or measures to be taken:

— in the event of malfunction of the instrument or its degradation as suggested by changes in its appearance that can affect performance;

— as regards the exposure of the instrument to reasonably foreseeable external influences or environmental conditions, e.g. magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature, as appropriate;

— as regards the risks of interference posed by the reasonably foreseeable presence of the instrument during specific diagnostic investigations, evaluations, therapeutic treatment or other procedures such as electromagnetic interference emitted by the instrument affecting other equipment.

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;

   EXAMPLES Risks related to handling and disposal of infectious or potentially infectious materials. known interferences that present significant risk

b) disposal of batteries;

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

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

NOTE 1 Information that enables users to reduce a risk is called “information for safety”. See ISO 14971.

NOTE 2 In some countries, authorities having jurisdiction can set local requirements for the contents of warnings and precautions and/or measures to be taken and limitations of use regarding the device. For example, in the European Union, the instructions for use give precautions related to materials incorporated into the device that contain or consist of substances which are carcinogenic, mutagenic or toxic for reproduction, or endocrine disrupting substances or that could result in sensitisation or an allergic reaction by the patient or user.

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, dissipated heat;

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;

EXAMPLE 1 A sample pipette delivery relative volume error is in the interval [–2 %; 2 %] (95 % confidence) from 5 µL to 20 µL.

EXAMPLE 2 A reagent pipette dispenses with a relative standard uncertainty of 2 % or less from 50 µL to 200 µL.

c) Performance of the IVD instrument.

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

EXAMPLES Carryover, sample volume, reagent volume, measuring time, measuring temperature, linearity.

7.9 Limitations

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

EXAMPLES Inappropriate sample, 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 that is required;

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

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

c) ordering information for reagents and consumables;

d) types of sample containers;

e) types of acceptable samples;

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

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

g) hardware adjustments, if required.

7.11 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, e.g. on a card to be attached to the instrument, a quick reference guide or video, can be helpful to the user.

7.12 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. Where appropriate, the control procedure shall specify reference to the traceability of the highest order available reference according to ISO 17511 that is used to assign values to the calibrators. Process for validation of quality control procedures can be found in ISO 15198.

Users are responsible for determining the appropriate quality control procedures for their laboratory and for being aware of applicable laboratory regulations.

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

7.13 Calculation of examination results

The mathematical approach, when examination results are calculated and where applicable any additional software or database required for the interpretation of the results, shall be provided.

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

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

7.14 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.

7.15 Emergency samples

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

7.16 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.

7.17 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 samples, instrument, components and accessories.