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Needle-based injection systems for medical use — Requirements and test methods —

Part 7:
Accessibility for persons with visual impairment

Systèmes d'injection à aiguille —

Partie 7: Titre de partie dans la langue secondaire

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ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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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 11608-7 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*.

ISO 11608 consists of the following parts, under the general title *Needle-based injection systems for medical use — Requirements and test methods*:

— *Part 1: Needle-based injection systems*

— *Part 2: Needles*

— *Part 3: Finished containers*

— *Part 4: Requirements and test methods for electronic and electromechanical pen-injectors*

— *Part 5: Automated functions*

— *Part 6: Bolus injectors*

— *Part 7: Accessibility for persons with visual impairment*

Introduction

Previous to this document, the ISO 11608 series of standards has not provided guidance to address the use of NIS by persons with visual impairment The reality, however, is that a significant number of NIS users have visual impairments and operate these devices, even though the user interfaces rely primarily on visual communication to provide the information needed for safe and effective use. The result is that users with visual impairment have difficulty and may be at greater risk when using these products.

Given the prevalence of visual impairment and the fact that many NIS target disease states (e.g. diabetes) with co-morbid conditions that can impair vision, efforts should be made to eliminate or minimize, where possible, device features that constitute obstructions to product use for users with visual impairment.

This addition to the 11608 series defines terms related to visual impairment and provides guidance to enable manufacturers to provide information to the user in other sensory formats (e.g. tactile, auditory). New and existing features that address the needs of users with visual impairment will also benefit a broader range of stakeholders by reducing problems associated with “off-label" use.

The global impact of healthcare costs on healthcare access is widely understood. Hence it is also the desire that this guidance be used, where possible, to expand the user base for a given device rather than creating “special” device designs exclusively for users with visual impairments. Such niche marketing is likely to be accompanied by higher costs and, therefore, reduced availability of those devices for the users who need them most. The alternative approach is the design of products (and environments) to be usable by all people, to the greatest extent possible, without adaptation or specialized design, i.e. "universal design"[1] The goal is to develop one design that will accommodate a variety of user limitations, whether those limitations are permanent, temporary or caused by environmental conditions.

For product design purposes, it should be assumed that some users will have moderate visual impairment but will be able to read large print and see high-contrast product features. Other users, however, will not be able to make use of any visual features and will instead require information to be provided through other sensory means (e.g. tactile or auditory). Therefore, this standard includes the requirement to provide information in visual formats that can be perceived and understood by people with moderate visual impairment and in non-visual formats (e.g., tactile or auditory) that can be perceived and understood by people with no useful vision.

In conjunction with other parts of the 11608 series, manufacturers are expected to follow a risk-based approach and employ human factors engineering during the design, development and manufacture of NIS serving this important user population.Existing products and those currently under development may not fulfill some of the requirements given by this International Standard. However, manufacturers would be well advised to follow its provisions when improving existing products or developing new products to obtain an even higher level of quality.

[1] The Center for Universal Design, 1997: The Principles of Universal Design. Available online at: http://www.ncsu.edu/ncsu/design/cud/about_ud/udprinciples.htm.

Needle-based injection systems for medical use — Requirements and test methods — Part 7: Accessibility for persons with visual impairment

1 Scope

This part of ISO 11608 specifies particular requirements to make needle-based drug delivery systems or NIS (Needle Injection System) accessible for persons with visual impairments. It applies to devices intended for patient or caregiver administration of medicinal products to humans.

This part of ISO 11608 covers requirements to allow for safe and correct handling of the NIS, including labelling, packaging, and instructions for use. It also includes requirements for training programs, if applicable.

NIS that are claimed appropriate for use by persons with visual impairments shall meet the applicable requirements of this part of ISO 11608.

This part of ISO 11608 does not address requirements for use of sharps containers by persons with visual impairments.

Although specifically intended to apply to needle-based injection systems, this part of ISO 11608 may be applied to NIS outside the ISO 11608 series as well, if they might be used by persons with visual impairments.

2 Normative references

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

ISO 11608-1:2015, *Needle-based injection systems for medical use - Requirements and test methods*

IEC 62366-1:2015*, Medical devices – Application of usability engineering to medical devices*

3 Terms and definitions

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

3.1
blindness
visual acuity less than 3/60; having no useful vision

3.2
functional vision
how a person functions when attempting visual tasks such as reading, orientation and mobility, activities of daily living, visual communication, and visual job skills

3.3
functional visual impairment
a significant limitation of visual capability that cannot be corrected by refractive lenses, medications, or surgery and results in difficulty accomplishing visual tasks that are important to the individual

3.4
moderate visual impairment
visual acuity between 6/18 and 6/60

3.5
needle-based injection system
NIS
injection system intended for parenteral administration by injection of medicinal products using a needle and a multi-dose or single dose container

[SOURCE: ISO 11608-1:2012, definition 3.9]

3.6
severe visual impairment
visual acuity between 6/60 and 3/60

3.7
visual acuity
sharpness of vision expressed as a fraction of normal vision

EXAMPLE The notation “6/12” means that a specific person can distinguish an image at a distance of 6 metres that a person with normal vision could distinguish at a distance of 12 metres.

3.8
visual impairment
sight loss that cannot be corrected using corrective lenses (e.g., glasses or contact lenses).

4 Requirements

4.1 Risk analysis requirements

The manufacturer's risk assessments shall consider all aspects of intended use of the NIS for medical purposes, including use by individuals without visual impairment as well as individuals with moderate visual impairment or blindness.

When conducting the risk assessment, it is important to accurately identify all user groups of the NIS and their functional characteristics. Some disease conditions (e.g. diabetes) and some medications (e.g. thorazine) can cause visual impairments and some user groups (e.g., elderly adults, who might be the patient or a lay caregiver) are more likely to have visual impairment. If there is a possibility of visual impairment amongst the NIS user groups, analysis of the potential effects of those impairments on the users’ interactions with the NIS shall be included in the risk assessment.

The assessment of the risks and benefits associated with use of the NIS shall consider the fact that for users with visual impairment the risks might be different from the risks for users without visual impairment. However, while the benefits of the medicinal product are the same for both user groups, for users with visual impairment the benefits of self-delivery of the medicinal product could be much greater.

4.2 General requirements

4.2.1 NIS design

The NIS shall be designed so that a user with moderate visual impairment or blindness can use it safely and correctly for its intended purpose, including, where applicable, filling the NIS with medicinal product and assembling components. The requirements in this clause may be fulfilled through the use of an accessory (e.g. separate device or mobile application).

NIS shall clearly indicate and distinguish the following states by visual and non-visual means, i.e. providing equivalent information in other sensory formats such as tactile, and/or audible formats:

— unused

— ready to deliver

— delivery initiated

— delivery completed

— end of useful life

NOTE The term “in use” which is included in ISO 11608 – 5 includes all the three of the states listed above: “ready to deliver, delivery initiated and delivery completed”.

a) The visual and non-visual information shall be consistent with each other. State indicators shall be persistent[2], repeatable, or retrievable to facilitate confirmation by the user while the NIS is in that state. Where applicable, the NIS shall allow the user to determine the deliverable dose by visual and non-visual means.

b) The NIS shall allow the user to assess the appearance of the medicinal product by visual means, e.g., through assistance from a sighted person, and where possible, non-visual means.

When the NIS requires the user to pre-set the dose, or the manufacturer pre-sets the dose, the NIS shall provide an indication, through visual and non-visual means of the dose that has been set.

c) Variable multi-dose NISs (system designations A and C, as defined in ISO 11608-1) shall be designed so that they indicate through visual and non-visual means the amount of medicinal product:

— delivered, or;

— not delivered (of the pre-set dose).

d) If the NIS contains batteries, it shall be designed to allow the user to determine the state of the power supply by visual and non-visual means.

e) The NIS shall enable the user to safely identify the location from which sharps will project using visual and non-visual means. Where retraction of the needle from the injection site is automatic, indication of the completion of needle retraction shall be provided by non-visual means.

f) Any means that are used to communicate to the user information needed for safe use shall not be compromised by any of the pre-conditioning tests (drop, damp heat, hot, cold, etc.) described in ISO 11608-1.

[2] Information presentation can be either persistent (constant) or transient (temporary). For example, a continuous audible tone would be persistent, whereas a single click or “beep” would be transient.

4.2.2 Packaging design

The NIS packaging shall be designed so that a user with moderate visual impairment or blindness can open it safely and correctly, without being harmed or damaging the NIS.

The packaging shall be designed so that the user can open it easily by hand, without an additional tool. Features provided to facilitate opening the packaging shall be readily apparent by visual and tactile means.

The packaging shall be designed to include appropriate retaining features to prevent inadvertent spillage of the package contents once the packaging is opened.

If assembly of the NIS is required, the components shall be packaged in a way that facilitates correct identification and assembly.

4.2.3 Design of information supplied by the manufacturer

The information supplied by the manufacturer shall be:

a) designed to enable safe and effective use of the NIS;

b) readable by users with moderate visual impairment;

c) presented in a format that is compatible with assistive reading technologies.

The NIS markings shall enable the user to access the same information required in ISO 11608-1 clause 13.2.2 by non-visual means.

NOTE The risk assessment could indicate that the NIS markings should enable the user to distinguish it from similar NIS in the same environment.

The packaging markings shall:

— be readable by users with moderate visual impairment, readily locatable by non-visual means, and compatible with assistive reading technologies.

NOTE Technologies that might be used to read the packaging markings include assistive reading technologies that utilize machine readable code, web browser links to websites, telephone, and/or magnification.

— enable the user to identify the contents, content description, and expiration date by visual means, and offer access to that information by at least one non-visual means.

5 Test methods

5.1 Verification testing

Testing shall be conducted to verify that the NIS design was implemented in accordance with the design specifications, including those features that make the NIS safe and effective for users with visual impairment.

NOTE Specifications for functions related to accessibility can include, but are not limited to, operating ranges, maximum and/or minimum levels and dimensional values of technical parameters. For further information see Annex A.

While lab-based testing and measurement of the accessibility-related user interface features can form part of a verification program for the product, NIS manufacturers shall be aware that appropriate usability validation testing will provide final evidence that the intended users can use the NIS safely and correctly.