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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 pour usage médical — Exigences et méthodes d'essai —

Partie 7: Accessibilité pour les personnes malvoyantes

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Foreword

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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).

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

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is 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: Needle-based injection systems containing electronics*

— *Part 5: Automated functions*

— *Part 6: On-body delivery systems*

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

Introduction

Prior to this part of ISO 11608, the ISO 11608 series 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 part of ISO 11608 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 population.

The purpose of this part of ISO 11608 is to assist manufacturers in developing NIS designs that will be usable for users with visual impairment but recognizes that those designs could be more usable also for users with no visual impairment. Taking this type of "universal design"[29] approach is preferable to the creation of "niche" products only for users with visual impairment, for which the market would be smaller and, consequently, the product cost likely would be higher. Applying universal design principles to extend access to users with visual impairment can increase the market size, thereby reducing product cost and enabling a broader patient population to access the NIS.

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 part of ISO 11608 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 ISO 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 fulfil some of the requirements given by this part of ISO 11608. However, manufacturers would be well advised to follow its provisions when improving existing products or developing new products to obtain a higher level of accessibility.

Guidance on transition periods for implementing the requirements of this International Standard is given in ISO/TR 19244.

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-based 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.

This part of ISO 11608 covers requirements for NIS that are claimed to be appropriate for use by persons with visual impairments.

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 within the ISO 11608 series, this part of ISO 11608 can be applied to NIS outside the ISO 11608 series as well, if they might be used by persons with visual impairments.

This part of ISO 11608 is written to address the needs of persons with all levels of visual limitations, including low, moderate, or severe visual impairment; legal, functional, or total blindness; and colour vision deficiencies.

Therefore, this part of ISO 11608 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.

For simplicity's sake, this range is described in this part of ISO 11608 as addressing the needs of individuals with moderate visual impairment or blindness.

NOTE NIS that are not claimed to be appropriate for use by persons with visual impairments need not meet these requirements, but manufacturers are encouraged to consider them.

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 11608-1:2014, *Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems*

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

IEC 62366-1,[1)] *Medical devices — Part 1: Application of usability engineering to medical devices*

1) Replaces IEC 62366.

3 Terms and definitions

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

3.1
colour vision deficiency
inability to distinguish certain shades of colour or in more severe cases, see colours at all

3.2
blindness
visual acuity (3.10) less than 3/60

Note 1 to entry: Having no useful vision.

Note 2 to entry: See Table A.1.

3.3
functional vision
way in which a person functions when attempting visual tasks, such as reading, orientation and mobility, activities of daily living, visual communication, and visual job skills

3.4
functional visual impairment
significant limitation of visual capability that cannot be improved by corrective lenses, medications, or surgery, and results in difficulty accomplishing visual tasks that are important to the individual

Note 1 to entry: See Annex A.

3.5
moderate visual impairment
visual acuity (3.10) between 6/18 and 6/60

Note 1 to entry: See Table A.1.

3.6
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 11608-1:2014, 3.9]

3.7
non-visual means
format that utilizes a sensory channel other than vision

Note 1 to entry: Braille is not widely used; therefore, it is not recommended as the only tactile format.

Note 2 to entry: Examples of non-visual means are channels for e.g. tactile, auditory, olfactory sensors.

3.8
severe visual impairment
visual acuity (3.10) between 6/60 and 3/60

Note 1 to entry: See Table A.1.

3.9
user interface
means by which the user and the medical device interact

[SOURCE: IEC 62366-1:2015, 3.26, modified]

3.10
visual acuity
sharpness of vision expressed as a fraction of normal vision

Note 1 to entry: See Annex A.

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

3.11
visual impairment
sight loss that cannot be improved by corrective lenses

Note 1 to entry: Corrective lenses can be glasses or contact lenses.

4 Requirements

4.1 Risk analysis requirements

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

When conducting the risk assessment, it is important to accurately identify all user groups of the NIS and any functional characteristics of each group that could affect their use of the NIS. 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. Some users of the NIS might have colour deficiency, which could be associated with other types of risks. 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.

As part of the risk analysis conducted according to ISO 14971, the manufacturers shall identify all use scenarios that could lead to a hazardous situation or harm and then implement risk control measures needed to reduce the risks to acceptable levels. The adequacy of the risk control measures shall be assessed in the summative evaluation of the NIS. See 5.2.

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. The analysis of risks shall include handling of the NIS, accurate dosing of the specific drug, and understanding of the information supplied by the manufacturer. While the benefits of the medicinal product are the same for both user groups, the benefits could be greater for users with visual impairment due to the ability to self-administer the medicinal product.

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 1 ISO 11608-5 uses the term “in use”, which includes three of the states listed above: “ready to deliver, delivery initiated, and delivery completed”.

The NIS design shall meet the following requirements.

a) The visual and non-visual information shall be consistent with each other. State indicators shall be persistent or confirmable 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.

NOTE 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.

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, either the amount of the pre-set dose delivered or the amount of the pre-set dose not yet delivered.

d) If the NIS contains batteries, it shall be designed to allow the user to determine the remaining battery charge 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. If a tactile means is used to identify and verify status of the needle, it shall be designed in such a way that the use of the tactile means itself will not lead to increasing risk of needle stick injury.

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.

Features provided to facilitate opening the packaging shall be readily apparent by visual and at least one non-visual means.

The packaging shall be designed 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.

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.

Specifications for functions related to accessibility, such as operating ranges, maximum and/or minimum levels, and dimensional values of technical parameters shall be verified. For further information, see Annex C.

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 formative and summative validation will provide final evidence that the intended users can use the NIS safely and correctly.

5.2 Summative evaluation (validation testing)

5.2.1 General

Where the intended user groups are identified as including people with visual impairment, such users shall be included in summative evaluation conducted on the NIS and its packaging and labelling.

The summative evaluation of the NIS shall be conducted according to IEC 62366-1 and include the user populations and context of use.

5.2.2 User populations

Summative evaluation of a NIS that follows this part of ISO 11608 shall include the intended users.

For the purposes of recruiting people with visual impairment to participate in summative evaluation of a NIS, and characterizing their level of impairment, measuring functional vision might be simpler and more appropriate and useful than measuring visual acuity. Standardized instruments are available for this purpose. The manufacturer shall provide a rationale for their choice to measure either functional vision or visual acuity, and the specific measurement instrument selected. See Annex A.

5.2.3 Context of use

The context of use for the NIS shall be considered in the risk assessment. All aspects of the context of use that could affect users' ability to use the NIS safely and correctly shall be incorporated into the summative evaluation.

Aspects of the context of use that are particularly important to users with visual impairment include any environmental conditions that could affect users' perception of information. For example, lighting conditions (e.g. low light or glare) can affect the ability of users with moderate visual impairment to perceive visual information provided by the user interface. Ambient noise levels and acoustic characteristics of the environment (e.g. reverberation) can affect the ability of users to perceive auditory information provided by the user interface. Cold temperatures can affect users' ability to perceive tactile information.

Another aspect of the context of use that is particular to users with visual impairments is use of assistive technologies. Some users will use glasses or magnifying technologies to perceive visual information. Some users will use sound amplifiers to perceive auditory information.

6 Test report

See ISO 11608-1 and IEC 62366-1.