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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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Contents

Page

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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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.

7 Information supplied by the manufacturer

7.1 General

7.1.1 Overview

All visual information required for safe and effective use of the NIS shall be perceptible and comprehensible to users with moderate visual impairment. Users with blindness shall be able to access the same information through non-visual means. The visual and non-visual information shall be consistent with each other.

7.1.2 Tactile information

Information can be communicated through tactile means.

Tactile information can be provided in formats such as raised characters, vibration, distinctly shaped controls, braille, and other features. The effects of degenerative diseases and neuropathy in the patient population of the intended NIS shall be considered in the design of any tactile communication methods.

NOTE See ISO/TR 22411:2008, 8.2.2.1 for guidance on suitable tactile markings. ISO/TR 22411:2008, 9.2.3.2, 9.2.3.3 and 9.2.4 provide guidance on the spatial and temporal resolution of the tactile sense, as well as the thermal sense. ISO 24503 provides requirements for improving the accessibility of consumer products used by persons with visual impairment, and in cases where visual information is not the primary sense used for accomplishing the task.

7.1.3 Auditory information

Information can be communicated by auditory means.

Auditory information can be provided in formats such as synthesized or recorded speech, melodies, clicking, beeping, or buzzing.

NOTE See ISO/TR 22411:2008, 8.2.2.2 for guidance on effective design of auditory feedback. ISO 24500 provides guidance for improving the usability and accessibility of auditory signals used in consumer products, thereby facilitating use by all people, including people with visual impairments and older people with age-related hearing impairments. ISO 24501 specifies methods for determining an appropriate sound level range for auditory signals, so that all product users, including people with age-related hearing loss, can hear them properly against interfering sounds.

7.1.4 Information provided in electronic format

Information can be communicated through electronic means.

Electronic information can be provided in formats such as codes or signals intended to interact with hand-held devices, dedicated readers, or assistive technologies.

NOTE One example of an electronic marking is a QR (quick response) code, which is a form or optically machine-readable image that conveys information such as text or a website address. ISO/IEC 18004 defines the requirements for the symbology, known as QR Code 2005.

7.2 Marking

7.2.1 Marking on the NIS

The NIS markings shall enable the user to access the same information required in ISO 11608-1:2014, 13.2.2, by non-visual means.

Flashing, blinking, scrolling, or flickering displays can be difficult for users with moderate visual impairment to read. Distracting or unnecessary information should not be presented to the user.

NOTE 1 The following International Standards provide useful guidance:

— ISO/TR 22411:2008, 8.5, 8.6 and 8.8 provide useful guidance on improving legibility and comprehension of text and graphic markings.

— ISO 24502 provides a method of calculating age-related luminance contrast that can be used for assessing and designing signs and visual displays so that they are clearly visible to older people.

NOTE 2 The risk assessment could indicate that the NIS markings should enable the user to distinguish it from similar NIS in the same environment.

7.2.2 Marking on the unit packaging

The markings on the packaging shall enable the user to access the same information required in ISO 11608-1:2014, 13.2.3 by visual and at least one non-visual means.

Markings shall be 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.

7.3 Instructions for use

All information in the instructions for use shall be available to users with visual impairment. This information shall be provided through visual means usable by persons with moderate visual impairment and through at least one non-visual means.

The instructions for use shall include information in clear language to facilitate use of the NIS by persons with visual impairment, including reference to all non-visual information provided by and markings on the NIS. For example, where applicable, the following information shall explain how to, safely and correctly,

— remove the parts of the NIS from the packaging,

— identify the parts of the NIS and necessary consumable components and assemble them correctly,

— determine how much medicinal product is in the NIS,

— fill the device with the medicinal product,

— combine separate components of medicinal products,

— conduct priming steps or other dose delivery preparation,

— set the dosage in the NIS,

— deliver a complete dose with the NIS,

— determine how much medicinal product was delivered by the NIS,

— remove and reinstall replaceable components,

— disassemble the NIS,

— dispose of the NIS or consumable components,

— detect the correct orientation of the battery or batteries, and

— perform troubleshooting.

NOTE See ISO/TR 22411:2008, 8.7 for guidance on written and spoken communication. ISO 11156 provides general guidance on increasing accessibility of packages and packaged products.

Additional information to consider when developing instructions for use for persons with visual impairment is given in Annex B.

If it is not possible to provide information necessary for safe and effective use of the NIS using non-visual means, e.g. inspection of the primary packaging and drug product, this possibility shall be considered as part of the risk assessment.

Annex A
(informative)

Measuring vision and visual impairment: Functional vision and visual acuity

A.1 General

Two distinctively different methods can be used to describe or measure vision and visual impairment: **functional vision** and **visual acuity** [5][6][7].

— **Functional vision** describes how well a person functions when attempting visual tasks such as reading, orientation and mobility, activities of daily living, visual communication, and visual job skills. It can be measured directly, by observation of the person performing a defined set of standardized visual tasks, or indirectly through a visual function questionnaire[5].

— **Visual acuity** is a measurement of how well an eye functions when a person attempts to see. It is the sharpness of vision expressed as a fraction of normal vision. It can be measured using an eye chart, optical instruments, or computerized tests. All of these tests should be administered under standard conditions, e.g. standardized light levels, viewing distance, time for response, and levels of errors allowed[6].

Recruitment of people with visual impairment to participate in summative evaluation of NIS requires measuring their vision in some way to ensure that the persons included in the testing represent the intended user population. Measurements of functional vision and visual acuity each have distinctive advantages and disadvantages. Therefore, either may be used in summative evaluation.

A.2 Measures of functional vision

Methods for measuring functional vision focus on how people are able to use their vision in everyday situations[7]. A common method is to use a short functional vision questionnaire to generate a numerical score. Many such questionnaires exist and can be found in published reports[8][9][10].

Two functional vision questionnaires that are widely used internationally and that have been validated for multiple eye conditions and translated into many languages are the following[8]:

— National Eye Institute Visual Function Questionnaires (NEI-VFQ and NEI-VFQ25) (US)[11][12][13];

— Visual Function Index (VF-14)[14].

Functional vision questionnaires have the following advantages.

a) **Reflects actual functioning.** Individuals with the same visual acuity may use different methods to enhance their ability to use remaining vision (e.g. by using particular eye movements and optimal lighting)[15]. Therefore, two people with the same visual acuity may have quite different levels of visual function. Measures of functional vision can reflect how each person would function when performing specific types of tasks[9], such as near vision scales that are related to self-administration of medication (e.g. reading the small print on a prescription bottle). In contrast, visual acuity tells you little about how well the individual is able to use vision for performing tasks under everyday conditions[5][16].

b) **Scores are stable.** Scores on functional vision questionnaires tend to be stable, reflect overall functioning, and correlate highly with other functional vision questionnaires[5][17]. In contrast,

with certain eye conditions, measurements of visual acuity can fluctuate throughout the day (e.g. changing with blood glucose levels).

c) **Easy to use.** These questionnaires can be administered orally in person, with pencil-and-paper, by computer, or on the telephone.

The disadvantages of measurements of functional vision include the following.

— **Self-reported.** Functional vision questionnaires inherently rely on subjective self-report rather than objective measurements. Although this may be the only way to measure a person's experience of visual impairment, all the common limitations of self-reported measures are inherent in this measurement method.

— **Not originally developed for screening.** The functional vision questionnaires were originally developed as outcome measures for studies of treatments for eye disease, not as a screening instrument. Specific score levels were not originally defined for moderate or severe visual impairment. However, several subscales, including the near and distance vision subscales, have been demonstrated to correlate highly with measured visual acuity in large populations[18]. Furthermore, because such questionnaires have been used extensively, cutoff scores for screening can be readily derived from large studies of eye disease treatments.

Cutoff scores:

The NEI-VFQ: This questionnaire contains several subscales that can be administered and scored separately. The subscales most appropriate for measuring vision for NIS are the near vision subscale, including optional near vision questions (items 5, 6, 7, A3, A4, A5.), and the distance vision subscale, including optional distance vision questions (items 8, 9, 14, A6, A7, A8)[19]. Based on standard scoring (0-100) of these two scales combined, and the results from numerous studies of eye disease treatments, the following cutoffs may be used[20][21][22][23]:

No or minimal visual impairment: ≥80

Moderate visual impairment: between 65 and 79

Little to no useful vision: ≤64

VF-14: This is a 14-item questionnaire. Based on standard scoring (0-100), and the results from numerous studies of eye disease treatments, the following cutoffs may be used[24][25][26][27][28]:

No or minimal visual impairment: ≥81

Moderate visual impairment: between 61 and 80

Little to no useful vision: ≤60

Because cutoff values for this use for both the NEI-VFQ and the VF-14 are not yet fully established, publication of new evidence may prompt adjustment of these values.

A.3 Measures of visual acuity

The method for measurement of distance visual acuity that is most familiar to many people is the Snellen chart, a high-contrast chart containing letters of progressively smaller size. (Similar charts with pictures are available for measuring visual acuity with non-readers.) The person stands 6 m (20 ft. away), with standardized light levels, and reads each line successively up to the level at which the letters cannot be read accurately. To generate a numerical score, a standard time for response and standard number of errors allowed for each line have been defined.

Other similar measurements exist for both distance and near visual acuity; these should also be administered in-person under standard conditions.

Measures of visual acuity have the following advantages:

a) **Objective.** These are objective measurements, not reliant on self-report.

b) **Levels for low vision are defined.** The visual acuity levels for mild, moderate, and severe low vision have standard definitions. (See Table A.1.) Therefore, use of these measurements for screening has been well-defined.

Measures of visual acuity have the following disadvantages:

— **May not be meaningful for visual functioning.** Although visual acuity levels defining low vision exist, those levels may not correlate well with actual visual functioning in everyday life. Variables that affect visual functioning include fluctuating vision, lighting levels and types (e.g. direct or indirect), and the person's ability to use remaining vision efficiently and effectively through learned scanning and focusing techniques. Therefore, two people with the same measured visual acuity may function quite differently when attempting visual tasks, with some accomplishing many visual tasks and others with the same visual acuity scarcely accomplishing any. Furthermore, with visual fluctuation, it is impossible to know how to interpret any given measured visual acuity; it may represent the individual's best, worst, or typical vision throughout the day. It may be impossible to know whether this measurement will reflect the person's visual acuity when the task in question must be performed. If visual acuity fluctuates with changing blood glucose, and a task such as administering insulin must be performed when blood glucose is high, the person may need to perform the task when visual acuity is not typical but at its worst.

— **May be time-consuming, expensive, and burdensome.** Visual acuity must be measured in person under standard conditions. When planning usability validation testing of NIS, the time necessary, cost for the project, and burden to participants of either performing visual acuity tests or obtaining medical records documenting recent visual acuity tests must be considered. This may represent significant effort and budgetary allocation.

Internationally, different notations are used to represent a person's visual acuity. For example, the notation "6/12" means a particular person can distinguish an image at a distance of 6 m that could be distinguished at a distance of 12 m by a person with normal vision.

In the US, the 20/… notation is commonly used as an equivalent notation, meaning that the same notation is used regardless of the testing distance. In Europe, the decimal notation of visual acuity is prominent, while in Britain (and former dominions) the 6/… notation prevails. Some people use a true Snellen fraction, where the numerator specifies the test distance. The left part of Table A.1 shows the ranges of vision loss defined in ICD-9-CM.[2)] The centre part of the table shows conversions between the different notations.

2) International Classification of Diseases, Ninth Revision, Clinical Modification.

Table A.1 — Visual acuity ranges and visual acuity notations

Ranges (ICD-9-CM)		**Equivalent notations**		**True Snellen fractions** (numerator = test distance)					**Magnification requirement**		**Visual acuity score (letter count)**
		Decimal	US	6.3 m	6 m (Britain)	5 m (Europe)	4 m (ETDRS)	1 m (low vision)	MAR (1/V)	Log MAR	
(Near-) Normal vision	Range of normal vision	1.6 1.25 **1.0** 0.8	20/12.5 20/16 **20/20** 20/25	6.3/4 6.3/5 **6.3/6.3** 6.3/9	6/3.8 6/4.8 **6/6** 6/7.5	5/3.2 5/4 **5/5** 5/6.3	4/2.5 4/3 **4/4** 4/5	1/0.63 1/0.8 **1/1** 1/1.25	0.63 0.8 **1.0** 1.25	−0.2 −0.1 **0** +0.1	110 105 **100** 95
	Mild vision loss	0.63 0.5 0.4 0.32	20/32 20/40 20/50 20/63	6.3/10 6.3/12.3 6.3/16 6.3/20	6/9.5 6/12 6/15 6/19	5/8 5/10 5/12.5 5/16	4/6.3 4/8 4/10 4/12.5	1/1.6 1/2 1/2.5 1/3.2	1.6 2.0 2.5 3.2	0.2 0.3 0.4 0.5	90 85 80 75
Low vision	Moderate vision loss	0.25 0.20 0.16 0.125	20/80 20/100 20/125 20/160	6.3/25 6.3/32 6.3/40 6.3/50	6/24 6/30 6/38 6/48	5/20 5/25 5/32 5/40	4/16 4/20 4/25 4/32	1/4 1/5 1/6.3 1/8	4 5 6.3 8	0.6 0.7 0.8 0.9	70 65 60 55
	Severe vision loss	**0.10** 0.08 0.063 0.05	**20/200** 20/250 20/320 20/400	**6.3/63** 6.3/80 6.3/100 6.3/125	**6/60** 6/75 6/95 6/120	**5/50** 5/63 5/80 5/100	**4/40** 4/50 4/63 4/80	**1/10** 1/12.5 1/16 1/20	**10** 12.5 16 20	**+1.0** 1.1 1.2 1.3	**50** 45 40 35
	Profound vision loss	0.04 0.03 0.025 0.02	20/500 20/630 20/800 0/1000	6.3/160 6.3/200 6.3/250 6.3/320	6/150 6/190 6/240 6/300	5/125 5/160 5/200 5/250	4/100 4/125 4/160 4/200	1/25 1/32 1/40 1/50	25 32 40 50	1.4 1.5 1.6 1.7	30 25 20 15
(Near-) Blindness	Near-blindness	0.016 0.0125 **0.01**	20/1250 20/1600 **20/2000**	6.3/400 6.3/500 **6.3/630**	6/380 6/480 **6/600**	5/320 5/400 **5/500**	4/250 4/320 **4/400**	1/63 1/80 **1/100**	63 80 **100**	1.8 1.9 **+2.0**	10 5 **0** ....
	Blindness	No light perception (NLP)									

Annex B
(informative)

Guidance for developing instructions for use for persons with visual impairment

B.1 Developing instructions for use for people with visual impairment

The steps described below are recommended in the design and assessment of the instructions for use of a NIS that might be appropriate for use by persons with visual impairment.

B.2 Arrange for consultation from experts in communication techniques and assistive technologies used by persons with visual impairment

— Consultants can provide current knowledge of available technologies and usage patterns for communication with persons with visual impairment.

— Consultants can assist in developing clear, non-visual descriptions of tactile and auditory features.

— Appropriate consultants could be knowledgeable technology users with visual impairment or professionals who develop or recommend technologies for persons with visual impairment.

B.3 Choose formats for the instructions that will satisfy the needs of your intended audience

— Instruction formats can include large print, braille, digital text (e.g. saved in a format that can be read using a text-to speech program), and/or audio.

— Each instruction format is likely to be preferred by some people.

— The best practice is to provide multiple options, allowing each user to choose a preferred format.

— When multiple options are not possible, audio format may be the most broadly useful. Audio can also be useful for sighted people.

B.4 Write verbal descriptions of graphical elements within the instructions

— Describe graphical elements (e.g. photographs, illustrations, diagrams, tables, charts, and graphs) in words.

NOTE Guidelines for describing visual elements can be found in the “Description Key” web site of the Described and Captioned Media Program.

— The principle of providing equitable information for audio readers can help guide the level of detail needed. (E.g. when listing self-care behaviours, a picture of a blood glucose meter requires only a general description; the same meter in an instruction manual could require a detailed description of the parts.)

— Check all verbal descriptions with consultants to ensure their clarity and completeness.

B.5 Use a table of contents to help users navigate the document

— If the printed edition has a table of contents, an alternate format edition should also be provided. List locations in ways that make sense for each format. For example, for large print editions, list page numbers; for audio editions, list tracks.

— Include page numbers from the original printed format to allow persons with visual impairment to discuss the instructions with sighted persons using the print edition.

B.6 Format the text appropriately

— Format text according to the National Instructional Materials Accessibility Standards (NIMAS) guidelines. NIMAS provides guidance for formatting text files to facilitate conversion to multiple alternate formats (e.g. to speech or braille).

NOTE Detailed instructions for NIMAS files can be found on the web site of the National Center on Accessible Instructional Materials.

— Format the text in short, simple documents using “style sheets” in a word processing program.

B.7 Test the instructional materials for usability

— Checking that the instructions for use are clear and useful for persons with visual impairment is vital. Writing of instructions by sighted people for blind people is cross-cultural communication.

— Test all formats of the instructions for use with individuals who are representative of the intended user populations.

— Consultants can also review drafts of the instructional materials but cannot take the place of summative evaluation by representative users.

Annex C
(informative)

Process for establishing a specification, test methods and verification related to 5.1

C.1 General

In order to make the NIS accessible to blind and visually impaired users, it is essential to identify the functions required for safe operation of the product.

The high priority needs of visually impaired users should be addressed by appropriate designs that address their needs and are suitable for their use scenarios.

An example of the process of design feature testing and specification development (incorporating usability testing with users with visual impairment) is given below.

C.2 Inputs

Initial inputs to the NIS development process include identification and definition of the intended users, the tasks that users will perform, and the environments in which the NIS is expected to be used. Inputs can also be derived from sources such as published literature and databases of post-market events.

Based on these inputs, manufacturers typically develop early design concepts into prototypes of varying levels of fidelity, e.g. from paper representations (low fidelity) to fully functional prototypes (high fidelity). These prototypes can be tested to identify the strengths and weaknesses of each user interface to determine how well the designs meet the users' needs and to assess how well the previously identified use-related risks have been controlled. These evaluations are often performed iteratively throughout the NIS design development process. Based on the results, the design can be revised and then retested. This process is known as formative evaluation.

A variety of formative evaluation techniques can be employed. One technique is expert review, in which people who are, for example, knowledgeable of the device type or user population assess the NIS user interface and identify ways in which it could be improved. Another technique is usability testing, in which NIS prototypes are used by people who are representative of the intended users of the NIS. This type of testing is typically performed under conditions of simulated use (e.g. with the injection delivered into an injection pad) with early prototypes of the NIS, the labelling or the training. The results are used to inform the design of the user interface as it evolves.

C.3 Establish specification

The results of formative evaluation can be used to establish specifications for the design of the system (including NIS, labelling, packaging, and training). Formative evaluation can also be used to improve the specifications in an iterative manner, testing repeatedly with the intended user groups to establish the limits of each specification.

One approach would be as follows.

— Approximate a specification for the intended feature with anticipated parameters and tolerances.

  — For example, an audible alarm with a frequency of “x” to “y” Hz and a sound pressure of “a” to “b” dB(A) to suit the hearing of user group 1.

— Test the feature at the tolerance limits with intended users and in the intended use environment (or a representative simulation thereof) to determine whether the users’ response to the feature is as intended throughout the specified range(s).

— Assess the users’ responses to determine whether or not the parameters and tolerances are appropriate.

— Revise or define a new specification according to the assessment of the responses.

— Repeat testing with users as necessary.

Another approach used to test the limits of the geometry and mechanical interactions that would deliver the function to the end user would be as follows.

a) Design a test method to measure the specified parameters.

b) Verify the test method to determine that it can repeatedly and reliably measure the parameter with appropriate resolution and accuracy.

   1) For example, an auditory output volume is specified as X ± Y dB(A) appropriate to the hearing of user group 1.

c) A font size is specified as Y.

   1) Usability testing with the intended users indicates that this size is appropriate.

   2) Verification testing is required to confirm that the font size is correctly represented on the device. A test method may be to measure the letter size on physical test samples and checking that it falls within the tolerance of the printing process.

C.4 Verify

Use the defined test method to verify that the final design meets the specified parameters and tolerances.

A recommended approach would be as follows.

— Approximate a specification for the intended feature with anticipated parameters and tolerances.

  — For example, an audible alarm with a frequency of “x” to “y” Hz and a sound pressure of “a” to “b” dB(A) to suit the hearing of user group 1.

— Test feature at the tolerance limits with intended users and in the intended use environment (or a representative simulation thereof) to determine whether the users’ response to the feature is as intended throughout the specified range(s).

— Assess the users’ responses to determine whether or not the parameters and tolerances are appropriate.

— Revise or define a new specification according to the assessment of responses.

— Repeat testing with users as necessary.

C.5 Test methods — Mechanical performance limits

This is to test the mechanical limits of the geometry and mechanical interactions that deliver the function to the end user.

— Design test method to measure the specified parameters.

— Verify test method to determine that it can repeatedly and reliably measure the parameter with appropriate resolution and accuracy.

Example:

a) Record that a volume is within ±dB(A).

b) Font size. A font size established by user testing requires confirmation that the physical font size is correctly represented on the device. A test method may be by measurement of the letter size on physical test samples and checking that it falls within the tolerance of the print process.

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