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

Part 5:
Automated functions

Systèmes d'injection à aiguille pour usage médical — Exigences et méthodes d'essai —

Partie 5: Fonctions automatisées

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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 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by ISO/TC 84 *Devices for administration of medicinal products and catheters*.

This second edition cancels and replaces the first edition (ISO 11608-5:2012), which has been technically revised.

Information about the revision history of the ISO 11608 series can be found in ISO 11608-1:20##.

A list of all parts in the ISO 11608 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

This document is applicable to needle-based injection systems (NIS) with automated functions (NIS-AUTO) primarily intended to administer medicinal products to humans. Because of the anticipated variation in the designs of NIS-AUTOs, it tends to specify the results of the design effort instead of the physical and construction requirements used as the basis for NIS-AUTO design, so that innovation in achieving the intended purposes is not unnecessarily restricted. As such, this document intends to address basic elements regarding the safety and performance of NIS-AUTOs.

Despite certain advantages for intentional interchangeability for containers designed for different auto-injection systems, as well as the potential risks of inadvertent interchangeability, this document avoids setting forth design specifications for the uniform size, shape and interface of such containers. It is left for future initiatives to build upon the specifications in this document.

ISO 11608-1 is the umbrella document of the ISO 11608 series. All other parts, including this document, are to be used in conjunction with ISO 11608-1.

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

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

Part 5: Automated functions

1 Scope

This document specifies requirements and test methods for needle-based injection systems with automated functions (NIS-AUTO), including but not limited to:

a) medicinal product preparation (e.g. reconstitution);

b) needle preparation;

c) needle hiding;

d) priming;

e) dose setting;

f) needle insertion;

g) injection depth control;

h) injection of the medicinal product;

i) recording;

j) disabling the NIS-AUTO;

k) needle retraction;

l) needle shielding;

m) needle removal.

This document does not cover remote communication from the NIS-AUTO.

Automated features not included in the list above shall be specified and tested in accordance with the principles of this document.

All references to "function" in this document are by definition to be construed as automated functions (see 3.2). This document does not apply to these functions if they are performed manually by the user.

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

1) To be published (revises ISO 11608-1:2012). Stage at time of publication: ISO/DIS 11608-1:2020.

ISO 23908:2011, *Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11608-1 and the following apply.

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

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

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

3.1
actuation
action which initiates a NIS-AUTO function (e.g. *needle insertion* (3.14)), carried out by the NIS-AUTO user (or by another *automated function* (3.2))

EXAMPLE Pressing the *NIS-AUTO* (3.9) against the injection site.

3.2
automated function
function which does not require user interaction after *actuation* (3.1)

Note 1 to entry: A dose counter is considered an automated function if it changes its state without any user interaction.

3.3
disabling
function that changes the state of the *NIS-AUTO* (3.9) such that it is not able to be refilled, reloaded, reset, or reactivated for dose delivery, which will allow the *NIS-AUTO* (3.9) to perform any subsequent injections (including single-dose and the last dose of multi-dose systems)

3.4
dose setting (and memory)
function which sets the dose to be delivered (dose setting) and/or displays the previously set dose (memory)

3.5
injection of medicinal product
function which delivers the dose

3.6
injection time
time from *actuation* (3.1) to completion of the *injection of medicinal product* (3.5) as described in the IFU

3.7
intended injection depth
range of distance from the skin surface to the point at which the medicinal product is intended to be delivered

Note 1 to entry: See Figures in Annex C.

3.8
medicinal product preparation
function which prepares the medicinal product for administration (e.g. reconstitution)

3.9
needle-based injection system with automated function
NIS-AUTO
injection system that delivers a medicinal product through a needle wherein one or a series of functions are initiated by an action of the user and controlled automatically by the injection system

Note 1 to entry: Accessories that perform automatic functions in combination with manual injection NIS-AUTOs are regarded as NIS-AUTO.

3.10
needle cover
cover provided over a needle in order to protect the needle from damage and users from injury prior to use

Note 1 to entry: A needle cover alone is not a sharps injury protection feature unless it complies with ISO 23908.

3.11
injection depth control
function which controls the *needle extension* (3.12) such that the medicinal product is delivered at the *intended injection depth* (3.7)

3.12
needle extension
axial distance from the patient end of the needle tip to the nearest part of the NIS-AUTO body (defining the point of contact with the patient adjacent to the injection site)

3.13
needle hiding
function which intentionally obscures the needle from the user's sight either before, during or after the injection cycle

Note 1 to entry: The needle hiding function only has a visual requirement. It is not subject to any physical or dimensional requirements intended to restrict access to the needle. It does not imply any increased level of safety from needle stick injuries.

3.14
needle insertion
function which inserts the needle into the injection site to the *intended injection depth* (3.7) prior to the injection of the medicinal product

3.15
needle preparation
function which prepares the needle for use (e.g. needle attachment, removal of *needle cover* (3.10), etc.)

Note 1 to entry: The needle preparation function may be a feature of the design and not a mechanical action. For example, a NIS cap may contain features that interact with the *needle cover* (3.10) and when the NIS cap is removed, the *needle cover* (3.10) is automatically removed.

3.16
needle removal
function which disconnects the needle from the NIS-AUTO fluid path

3.17
needle retraction
function which removes the needle from the target tissue to a predefined position inside the *NIS-AUTO* (3.9)

3.18
needle shielding
function which covers the needle before and/or after the injection cycle to reduce the likelihood of direct contact with the needle

Note 1 to entry: Needle shielding alone is not a sharps injury protection feature unless it complies with ISO 23908.

3.19
priming
function that makes the dosing mechanism of the *NIS-AUTO* (3.9) ready for dose administration (e.g. removing the air from the fluid path)

Note 1 to entry: *Needle preparation* (3.15) and fluid path connection should be considered separately.

3.20
recording
function which records information (e.g. dose counter)

Note 1 to entry: A *NIS-AUTO* (3.19) may include several different, possibly related, recording functions, which record different pieces of information related to the dose administered.

4 Requirements

4.1 General requirements

a) Any automated function considered a primary function shall be verified in accordance with ISO 11608-1.

b) Where the completion of an automated function is intended to be communicated to the user, it shall be apparent by visual means; and either tactile or audible means (i.e. visual and tactile, visual and audible) unless otherwise specified in this document.

c) Users shall be able to clearly distinguish between a NIS-AUTO that is unused, in use, used or disabled or requiring another "setup" step before it can be used again. For automated functions that change the state of the NIS-AUTO, a visual indication of the NIS-AUTO state shall be provided (e.g. ready for use in use, disabled or other states relevant for the particular NIS-AUTO).

d) Where the design of a NIS-AUTO allows manual operations to be performed in a sequence other than that specified in the instructions for use, the risk assessment shall address the risks of out-of-sequence operation.

e) Actuation of each automated function shall meet the following requirements:

   1) Actuation of injection: A minimum of two manual actions shall be required in order to initiate injection, e.g. from locked to unlocked state/ready for injection, then press to actuate. A multi-dose/use injection system with automated functions, once actuated, shall not allow an additional actuation without a separate and distinct action prior to a subsequent actuation.

   2) Actuation shall be tested in accordance with 5.3.

f) Automated functions shall not interfere with the primary functions of the NIS-AUTO.

g) For each automated function included within the NIS-AUTO design, the manufacturer shall apply the applicable requirements in this paragraph and perform testing in accordance with Clause 5. Where the design does not include the automated function, or does not automate the function, the relevant requirements of Clause 4 do not apply, and testing in accordance with the sections of Clause 5 is not needed. Refer to Table 1 for a matrix of the specific requirements and test methods for each automated function.

Table 1 — Requirements and test methods for automated functions (Ref. 4.1)

Automated function	Requirement	Test method
Medicinal product preparation	4.2 Medicinal product preparation	5.4 Medicinal product preparation
Needle preparation	4.3 Needle preparation	5.5 Needle inspection
Needle hiding	4.4 Needle hiding	5.6 Needle hiding
Priming	4.5 Priming	5.7 Priming
Dose setting	4.6 Dose setting	Per risk assessment
Needle insertion	4.7 Needle insertion	5.5 Needle inspection
Needle extension control	4.8 Injection depth control	5.8 Needle extension
Inject medicinal product	4.9 Dose delivery	5.10 Dose accuracy 5.9 Injection time
Recording	4.10 Device function information	Per risk assessment
Disabling	4.12 Disabling the NIS-AUTO	5.12 Disabling the NIS-AUTO
Needle retraction	4.11 Needle retraction	5.10 Dose accuracy 5.11 Retracted position
Needle shielding	4.13 Needle shielding	5.13 Needle shielding
Needle removal	4.14 Needle removal from the NIS-AUTO	Test method references included in requirement
NOTE Statistical requirements are specified in ISO 11608-1.		

4.2 Medicinal product preparation

Automated medicinal preparation shall not have an adverse impact on the medicinal product. The NIS-AUTO shall indicate to the user that the automated medicinal product preparation has been completed by at least visual means.

If risk assessment determines that it is necessary for the user to confirm that the medicinal product has been properly prepared, then the NIS-AUTO shall:

a) allow the user to perform visual inspection of the medicinal product; and/or

b) provide feedback that the medicinal product has been properly prepared.

Medicinal product preparation shall be tested in accordance with 5.4.

4.3 Needle preparation

The needle shall not be damaged by the automated function (needle attachment, removal of needle cover, etc.). If any portion of the needle preparation is an automated function and involves piercing of an elastomeric component the NIS-AUTO shall meet the requirements for coring in accordance with ISO 11608-3:20##, 4.2.3. The NIS-AUTO shall indicate to the user that the automated needle preparation has been completed by at least visual means.

After needle preparation there shall be no obvious damage to the needle and the patient end needle point shall appear sharp and free from feather edges, burrs and hooks.

Needle preparation shall be tested in accordance with 5.5.