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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

Reference number
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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).

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

This document was prepared by Technical Committee ISO/TC 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.

The main changes are as follows:

— this document has been clarified to explain that an automated function is one which does not require user interaction after the action which initiates the function, including designating injection depth control as automated when the user does not have control over the depth to which the needle is inserted, even where needle insertion is performed manually.

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.

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Introduction

This document is applicable to needle-based injection systems (NIS) with automated functions (NIS-AUTO) primarily intended to administer medicinal products to humans. In order to support device innovation and design, this document has been written in a format that describes the output of the design effort rather than prescribing the exact form of construction of the NIS-AUTO This document should be used in conjunction with ISO 11608-1.

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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 automated functions in needle-based injection systems with automated functions (NIS-AUTO).

General requirements are provided for all automated functions. In addition, specific requirements are provided for the following automated functions:

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 of device functions;

NOTE This document does not cover remote communication from the NIS-AUTO (pertains to wired and wireless communication transfer from the NIS auto).

j) disabling the NIS-AUTO;

k) needle retraction;

l) needle shielding;

m) needle removal.

All references to "function" in this document are by definition construed as automated functions (see 3.2). This document does not apply to functions that 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 11608-1:2022, *Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems*

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ISO 11608-3:2022, *Needle-based injection systems for medical use — Requirements and test methods — Part 3: Containers and integrated fluid paths*

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 terminology databases for use in standardization at the following addresses:

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

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

3.1
actuation
user action that initiates an automated function

EXAMPLE *Needle insertion* (3.13). Pressing the *needle-based injection system with automated function* (3.18) against the injection site.

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

Note 1 to entry: Dose counting.

3.3
disabling
function that changes the state of the *needle-based injection system with automated function* (*NIS-AUTO*) (3.18) such that it is not able to be refilled, reloaded, reset, or reactivated for dose delivery, which will allow the *NIS-AUTO* to perform any subsequent injections (including single-dose and the last dose of multi-dose NIS-AUTOs)

3.4
dose setting
function that sets the dose to be delivered

3.5
injection depth control
function or feature that controls the *needle extension* (3.11) such that the medicinal product is delivered at the *intended injection depth* (3.8)

3.6
injection of medicinal product
function that delivers the dose

3.7
injection time
time from initiation to completion of the *injection of medicinal product* (3.6) as described in the instructions for use

Note 1 to entry: The injection time that might be indicated in the instructions for use (IFU, sometime called hold time) can be the same or greater than the measured injection time, based on use risk approach.

Note 2 to entry: There can be a delay from actuation to initiation of injection that might be indicated in the IFU which might be measured and verified separately as determined by risk approach.

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3.8
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.

3.9
medicinal product preparation
function that prepares the medicinal product for administration

EXAMPLE Reconstitution, filling of reservoir.

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

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

3.11
needle extension
distance from the patient end of the needle tip to the nearest part of the *needle-based injection system with automated function* (3.18) body

Note 1 to entry: The nearest part of the needle-based injection system with automated function body is the point of contact with the patient adjacent to the injection site.

Note 2 to entry: See Annex C for more details.

3.12
needle hiding
function that intentionally obscures the needle from the user's sight before, during and/or after the injection cycle

3.13
needle insertion
function that inserts the needle into the injection site to the *intended injection depth* (3.8) prior to the *injection of the medicinal product* (3.6)

3.14
needle preparation
function that prepares the needle for use

Note 1 to entry: Needle attachment, removal of *needle cover* (3.10).

3.15
needle removal
function that disconnects the needle from the *needle-based injection system with automated function* (3.18) fluid path

3.16
needle retraction
function that removes the needle from the target tissue to a predefined position inside the *needle-based injection system with automated function* (3.18)

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3.17
needle shielding
function that 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 conforms with ISO 23908.

3.18
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: A manual needle-based injection system with accessories that perform automatic functions are regarded as NIS-AUTO.

3.19
persistent visual indication
visual indication that remains in place until the state of the needle-based injection system changes or until the end of the needle-based injection system use-life

3.20
recording
function that records information

EXAMPLE Dose counter.

Note 1 to entry: A *needle-based injection system with automated function* (3.18) might 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) Automated functions shall be verified in accordance with the design verification approach in ISO 11608-1, including sampling plan and data analysis, applying the requirements and test methods in this document.

b) Where the completion of an automated function is intended to be communicated to the user, the needle-based injection system (NIS) shall indicate by visual, audible or tactile means, or any combination of these that the function has been completed unless otherwise specified in this document. These means should be appropriate to the intended use of the NIS.

c) Users shall be able to clearly distinguish between a NIS-AUTO that is unused, in use, used or disabled or requiring another user action such as a "setup" step before it can be used again. For automated functions that change the state of the NIS-AUTO, a persistent 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

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