INTERNATIONAL STANDARD

ISO 11608-5

Second edition
2022-04

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
ISO 11608-5:2022(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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 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.

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.

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*

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.

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)

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

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 compromise the primary functions of the NIS-AUTO.

g) For each automated function included within the NIS-AUTO design, testing in accordance with Clause 5 shall be performed. If the function is not included or is not automated within the design, the relevant requirements of Clause 4 do not apply and testing in accordance with Clause 5 shall not be performed. Table 1 provides a matrix of the specific requirements and test methods for each automated function.

h) Where requirements in this document provide a test method without acceptance criteria, a specification and acceptance criteria shall be established for the automated function appropriate to the intended use of the NIS-AUTO and using a risk-based approach.

i) Where this document does not provide requirements and/or a test method, there shall be established a specification, acceptance criteria, and a method of verifying the automated function appropriate to the intended use of the NIS-AUTO and using a risk-based approach.

Table 1 — Requirements and test methods for automated functions

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	Use the risk-based approach as specified in 4.1 i)
Needle insertion	4.7 Needle insertion	5.5 Needle inspection
Injection depth control	4.8 Injection depth control	5.8 Needle extension
Injection of the medicinal product	4.9 Dose delivery 4.8 Injection depth control	5.10 Dose accuracy 5.9 Injection time
Recording of device functions	4.10 Device function information	Use the risk-based approach as specified in 4.1 i)
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	Use the risk-based approach as specified in 4.1 i)
NOTE Statistical requirements are specified in ISO 11608-1.		

4.2 Medicinal product preparation

Automated medicinal product preparation shall not compromise 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 11608-3:2022, 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 (e.g. kinked or bent lumen) and the patient end needle point (e.g. free from feather edges, burrs and hooks).

Needle preparation shall be tested in accordance with 5.5.

4.4 Needle hiding

If automated needle hiding is applicable before, during or after injection, the needle shall not be visible when the NIS-AUTO is placed against the injection site, when tested in accordance with 5.6.

Post-injection needle hiding shall not be considered to be needle shielding.

NOTE 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.

4.5 Priming

Dose accuracy testing shall be performed once priming is complete. The NIS-AUTO shall indicate to the user that the automated priming has been completed by at least visual means.

Priming shall be tested in accordance with 5.7.

4.6 Dose setting

Following automated dose setting the NIS-AUTO shall provide an indication that the dose has been set by at least visual means.

It shall be verified that the input(s) to the automatic dose setting function result in the intended set dose.

A test method shall be specified applying the risk-based approach specified in 4.1 i).

4.7 Needle insertion

The needle shall not be damaged by the automated feature, when tested in accordance with 5.5.

NOTE See requirement 4.3 for examples of needle point damage.

4.8 Injection depth control

When the design is such that the user does not have control over the depth to which the needle is inserted, the insertion depth shall be within the intended insertion limits specified, when tested in accordance with 5.8.

NOTE See Annex C for more details.