
**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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Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Requirements	4
4.1 General requirements	4
4.2 Medicinal product preparation	5
4.3 Needle preparation	6
4.4 Needle hiding	6
4.5 Priming	6
4.6 Dose setting	6
4.7 Needle insertion	6
4.8 Injection depth control	6
4.9 Dose delivery	7
4.10 Recording of device functions	7
4.11 Needle retraction	7
4.11.1 Completion of dose delivery	7
4.11.2 Needle retraction distance	7
4.11.3 Communication of completion	7
4.12 Disabling the NIS-AUTO	7
4.13 Needle shielding	8
4.13.1 General	8
4.13.2 Needle shielding before injection	8
4.13.3 Needle shielding after injection	8
4.14 Needle removal from the NIS-AUTO	8
5 Test methods	8
5.1 General	8
5.2 Test conditions	9
5.3 Actuation	9
5.4 Medicinal product preparation	9
5.5 Needle inspection	9
5.6 Needle hiding	9
5.7 Priming	10
5.8 Needle extension	10
5.9 Injection time	10
5.10 Dose accuracy	11
5.11 Retracted position	11
5.12 Disabling the NIS-AUTO	11
5.13 Needle shielding	11
5.13.1 Needle shielding before and after injection	11
5.13.2 Needle shielding after free fall	11
6 Information supplied with the NIS-AUTO	11
Annex A (informative) Rationale for requirements	12
Annex B (informative) Example of a test method for dose accuracy at intended injection depth	14
Annex C (informative) Needle extension and intended injection depth	16
Bibliography	22

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.