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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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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

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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).

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.

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.

4.9 Dose delivery

The dose accuracy shall be confirmed according to 5.10.

The dose delivery shall be completed within the specified injection time, as determined through risk assessment. The injection time shall be tested in accordance with 5.9.

The risk assessment shall address the potential harm to the patient of any portion of the medicinal product that might be delivered outside the intended injection depth due to the automated dose delivery.

The NIS-AUTO shall provide confirmation of completion of the automated injection by at least a persistent visual indication. This indication shall be reset between injections for multi-dose NIS-AUTOs.

4.10 Recording of device functions

Where the NIS-AUTO includes a feature, which records information related to the device function, the parameters of the information intended to be provided shall be specified applying the risk approach. A test method shall be specified applying the risk-based approach specified in 4.1 i).

4.11 Needle retraction

4.11.1 Completion of dose delivery

The sequence and timing of the retraction shall not cause incomplete delivery of the medicinal product to the intended injection depth.

This requirement can be verified as a separate study or can be verified during full dose accuracy testing using the method in 5.10.

The risk assessment shall address the potential harm to the patient of any portion of the medicinal product that might be delivered outside the intended injection depth due to the automated retraction.

4.11.2 Needle retraction distance

After needle retraction, the needle tip shall be sub-flush to the skin contact surface of the NIS-AUTO (defining the point of contact with the patient adjacent to the injection site) such that the retracted position ensures that the needle is completely retracted from the patient's tissue when measured in accordance with the method described in 5.11 or other means. An adjustment to the needle retraction specification might be required for those NIS-AUTOs that, when pressed against the skin, cause skin deformation, e.g. skin doming as shown in Figure C.1. Any adjustment to this specification shall be determined by risk assessment.

Needle retraction shall only be considered to be needle shielding if the NIS-AUTO meets the requirements of 4.13.

4.11.3 Communication of completion

It shall be determined by risk assessment, if the NIS-AUTO needs to indicate to the user if the needle has retracted.

4.12 Disabling the NIS-AUTO

Disabling of the NIS-AUTO (single-dose NIS-AUTOs or last dose from multiple-dose disposable NIS-AUTOs) shall take place after either or both of the following have occurred:

a) the injection is completed;

b) the NIS-AUTO is removed from the body.

It shall not be possible to disable the NIS-AUTO at any time before it has completed or abandoned/aborted its intended function. After completion of the disabling function, the NIS-AUTO shall not be able to be put into a state (e.g. refilled, reloaded, reset), which will allow it to perform any subsequent injections.

The disabling feature of the NIS-AUTO shall be tested in accordance with 5.12.

4.13 Needle shielding

4.13.1 General

Automatic needle shielding shall not compromise the NIS-AUTO intended function.

Needle shielding shall be tested in accordance with 5.13.

4.13.2 Needle shielding before injection

When shielded, the needle tip shall be sub-flush to the skin contact surface of the NIS-AUTO (defining the point of contact with the patient adjacent to the injection site).

Needle shielding before injection shall be tested in accordance with 5.13.1.

4.13.3 Needle shielding after injection

Once needle shielding has been activated, after the NIS-AUTO has completed its intended use, the feature shall meet the requirements of ISO 23908:2011, 4.3.

The force required to override the needle shielding feature, shall be determined by risk assessment. For NIS-AUTOs, where the needle shielding feature is also used to activate the NIS-AUTO, the overriding force shall be at least 2 times the maximum actuation force specified for the NIS-AUTO.

In addition, if needle shielding after injection is a primary function, the requirements of ISO 23908:2011, 4.3 shall be met after free fall when tested in accordance with 5.13.2.

NOTE The NIS-AUTO might provide a passive automated function (definition of passive safety feature is given in ISO 23908), distinct from needle shielding, which is designed to minimize the risks of accidental sharps injury.

Sharps injury protection cannot be claimed unless the NIS-AUTO meets the requirements of ISO 23908.

4.14 Needle removal from the NIS-AUTO

Automatic needle removal shall not compromise the NIS-AUTO intended function.

Automated needle removal shall not compromise the operation of a sharp injury protection feature (when provided) and shall allow for safe sharps disposal without manual handling of the needle.

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

5 Test methods

5.1 General

NOTE An overview of test methods is given in Table 1.

5.2 Test conditions

Automated functions that are determined through risk assessment to be primary functions shall be verified to meet the requirements of this document after pre-conditioning and in-use requirements in accordance with ISO 11608-1.

Unless otherwise specified, all tests and test evaluations shall be performed at standard atmosphere conditions as defined in ISO 11608-1.

5.3 Actuation

Perform each of the manual steps needed to actuate an automated function according to the instructions for use, and make measurements, where appropriate (for example, torque to rotate a safety lock or force to operate a button).

Confirm that each manual step meets its requirements and that the automated function is actuated as intended.

Perform the steps in each of the allowed sequences, where the design allows multiple sequences of operation to actuate the automated function. In whichever order the steps are performed, the NIS-AUTO shall not start the automated function until all steps are completed.

NOTE Requirement(s) defined in 4.1 e).

5.4 Medicinal product preparation

Operate the NIS-AUTO in accordance with the instructions for use. Confirm that the medicinal product meets the requirements in ISO 11608-1:2022, 5.6 s).

NOTE Requirement(s) defined in 4.2.

5.5 Needle inspection

Prepare the needle in accordance with the instructions for use.

Visually inspect the needle using magnification of 2,5× and environmental lighting conditions of ≥750 lx.

NOTE Requirement(s) defined in 4.3 and 4.7.

5.6 Needle hiding

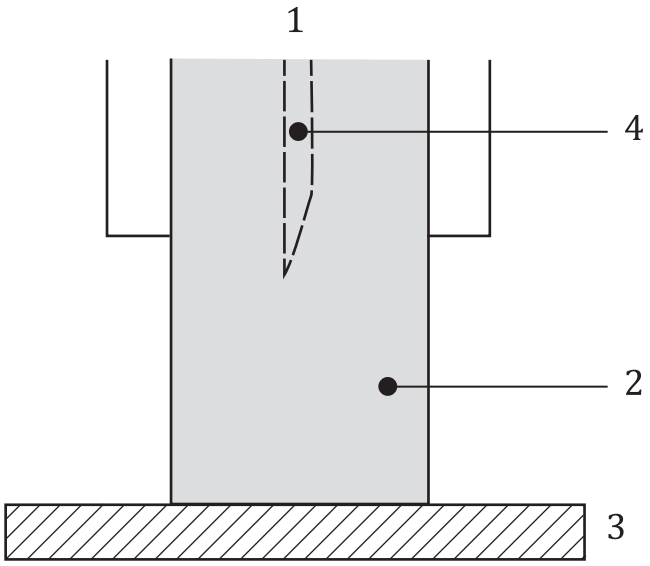
Prepare and operate the NIS-AUTO in accordance with the instructions for use using a test surface to represent the injection site as shown in Figure 1.

Check that

a) the needle is not visible through the needle hiding feature when the NIS-AUTO is in contact with the test surface, and

b) the needle does not protrude beyond the needle hiding feature when the NIS-AUTO is not in contact with the test surface.

NOTE Requirement(s) defined in 4.4.



Key

1 NIS-AUTO (before or after injection)
2 example of a needle hiding feature
3 test surface
4 needle (hidden)

Figure 1 — Example of needle hiding test set-up

5.7 Priming

Perform air removal and/or priming in accordance with the instructions for use. Following this, confirm the NIS-AUTO delivers the volume of medicinal product specified in the requirements in accordance with ISO 11608-1.

NOTE Requirement(s) defined in 4.5.

5.8 Needle extension

Measure the needle extension when operated in accordance with the instructions for use. Measurement can be performed by mechanical, optical or other means, but shall not affect the position of the needle tip.

NOTE 1 See Annex C for more method details.

NOTE 2 Requirement(s) defined in 4.8.

5.9 Injection time

Direct and indirect methods can be applied to measure injection time (e.g. use of high-speed camera, gravimetric reading, stream detection with laser, etc.)

The delivery of the medicinal product may or may not be in a single continuous stream. The determination as to the flow characteristics that represent the time of delivery shall be justified and documented.

NOTE 1 Injection time can be verified as a separate study, or can be verified during full dose accuracy testing applying the method(s) in Annex B.

NOTE 2 Requirement(s) defined in 4.9.

5.10 Dose accuracy

Dose accuracy shall be determined in accordance with ISO 11608-1.

For NIS-AUTOs that combine injection depth control, needle insertion and/or retraction with the injection, dose accuracy testing shall be modified to determine the accuracy of the dose delivered at the intended injection depth.

NOTE 1 See example in Annex B.

NOTE 2 Requirement(s) defined in 4.7, 4.8, 4.9, and 4.11.1.

5.11 Retracted position

Operate the NIS-AUTO in accordance with the instructions for use.

At the end of the retraction function, measure the axial distance from the needle tip to the skin contact surface of the NIS-AUTO body (defining the point of contact with the patient adjacent to the injection site).

NOTE Requirement(s) defined in 4.11.2.

5.12 Disabling the NIS-AUTO

Operate the NIS-AUTO in accordance with the instructions for use.

Verify that the NIS-AUTO was not disabled at any time before it completed or abandoned/aborted its intended use.

Subject the NIS-AUTO to potential routes of refilling, reloading or resetting in accordance with the risk assessment, to verify that the NIS-AUTO cannot perform any subsequent deliveries after disabling according to 4.12.

NOTE Requirement(s) defined in 4.1 a), 4.1 f) and 4.12.

5.13 Needle shielding

5.13.1 Needle shielding before and after injection

Determine the location of the needle tip in relation to the skin contact surface of the NIS-AUTO body, which is the point of contact with the patient adjacent to the injection site.

NOTE Requirement(s) defined in 4.13.

5.13.2 Needle shielding after free fall

Determine the “worst case” free fall orientation to challenge needle shielding by risk assessment. If all orientations are considered equivalent, a justification should be documented as to why a single set of samples can be tested and be representative.

Select a new set of samples and perform an injection in accordance with the instructions for use. Following completion of the needle shielding function, subject each sample to free fall in a non-turbulent way from a height of at least 1 000 mm onto a test surface as defined in ISO 11608-1:2022, 6.3 in the orientation determined by risk assessment.

NOTE Requirement(s) defined in 4.13.3.

6 Information supplied with the NIS-AUTO

The requirements in ISO 11608-1 shall apply.

Annex A
(informative)

Rationale for requirements

A.1 General

This annex contains rationale statements for some of the requirements in this document. It is included to provide additional information to the user.

A.2 Preparation

A.2.1 General

Since NIS-AUTOs that are covered by this document have one or more automated functions, 4.1.e) helps to ensure that the user cannot inadvertently initiate steps out of sequence if that order is important to the proper and safe functioning of the NIS-AUTO.

A.2.2 Medicinal product preparation

Since the user does not have the ability to control medicinal product preparation (e.g. reconstitution) for the NIS-AUTO (and the manufacturer cannot ensure proper medicinal product preparation through training), 4.2 requires the manufacturer to ensure that the automated function carries out such preparation in an appropriate and consistent manner.

Visibility of medicinal product might not be needed if, for example:

a) the NIS-AUTO has an active sensor to confirm that the medicinal product has been properly prepared;

b) the reliability of the medicinal product preparation has been confirmed;

c) the medicinal product is photosensitive;

d) the therapy would be affected by the user checking for the integrity of the medicinal product (e.g. emergency drug).

A.2.3 Needle preparation

The term “needle preparation” includes any preparatory steps the user might be required to perform prior to initiation of any automated steps, e.g. attaching the needle or removing the cover.

A.2.4 Dose setting

Subclause 4.6 describes automated dose setting of a previously set dose, rather than the utilization of post-injection memory on the NIS-AUTO.

A.3 Injection

A.3.1 Actuation of injection

Subclause 4.1 e) is included for user safety, by eliminating or reducing the potential for inadvertent actuation and triggering of any kind of automated NIS-AUTO (including dose delivery).

In addition, in the special case of a multi-dose or multi-use NIS-AUTO, this requirement is intended to reduce or eliminate the potential for inadvertent second (or subsequent) actuations without an explicit user-initiated step between each subsequent actuation.

A.3.2 Needle insertion

Subclause 4.7 is included to ensure that automation of the needle insertion function does not cause damage to the needle.

A.3.3 Injection depth control

Since NIS-AUTOs that fall within the scope of this document might control the extent to which the needle is inserted into the patient by limiting the amount the needle is extended from the NIS-AUTO, 4.8 requires that automated injection depth control be tested by measuring the needle extension in order to ensure the intended insertion distance is met and the dose is delivered to the to the intended injection depth.

A.3.4 Injection of the medicinal product

Since NIS-AUTOs covered by this document might automate the injection of the medicinal product, 4.9 requires that the user should be provided with persistent visual indication that this function has occurred.

A.3.5 Needle retraction

Subclause 4.11 addresses the retraction of the needle from the injection site.

It mandates that any automated needle retraction take place after the injection of the medicinal product has been completed.

A.3.6 Disabling the NIS-AUTO

Subclause 4.12 addresses both single-dose NIS-AUTOs and after the last dose from multi-dose disposable NIS-AUTOs. It is not applicable to each individual injection of such a multi-dose NIS-AUTO.

The purpose of 4.12 is to ensure that the NIS-AUTO cannot be unintentionally disabled.

A.3.7 Needle shielding

Subclause 4.13 does not cover needle stick injury protection. These requirements are given in ISO 23908.

A.3.8 Needle removal from the NIS-AUTO

Further requirements can be found in ISO 23908.

Annex B
(informative)

Example of a test method for dose accuracy at intended injection depth

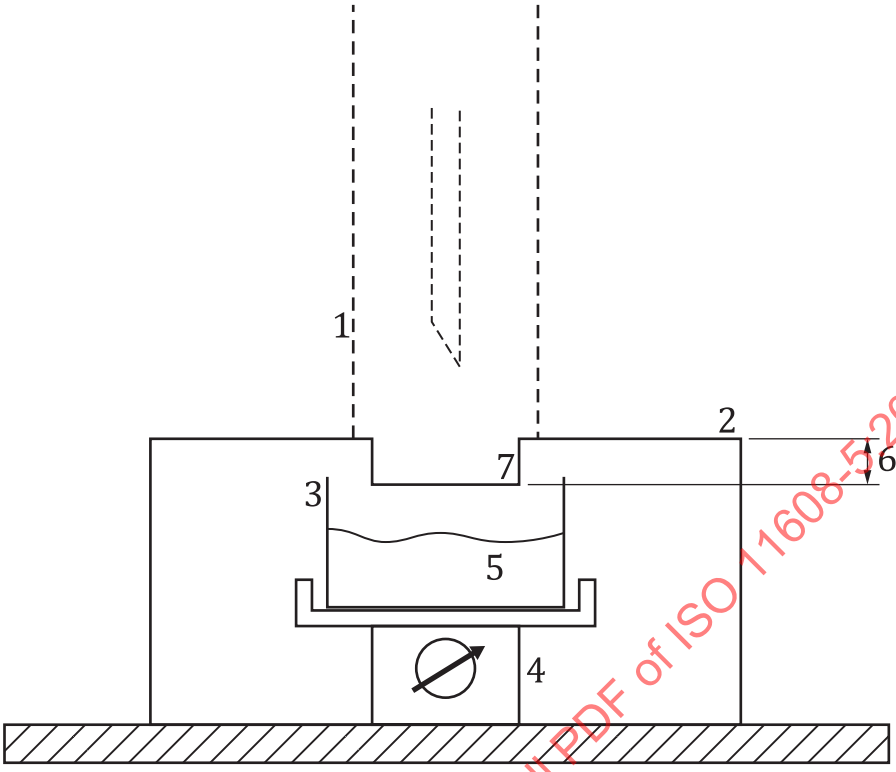
B.1 General

This annex contains an example of a test method for dose accuracy at intended injection depth. It is included to provide additional information to the user.

B.2 Dose accuracy with membrane

Using the test method specified in Figure B.1, a membrane shall be placed over the measurement container offset from the surface around the opening of the NIS-AUTO, such that its upper surface is at the minimum intended injection depth.

The volume of medicinal product delivered above the minimum injection depth shall be excluded from the calculation of dose accuracy. The membrane shall not allow any liquid to flow into the measurement container other than that through the needle and shall not adversely affect the needle insertion or retraction.



Key

1 NIS-AUTO
2 test fixture (not connected to scale)
3 measurement container
4 scale
5 liquid
6 minimum intended injection depth
7 membrane

Figure B.1 — Example of dose accuracy test set-up

Annex C
(informative)

Needle extension and intended injection depth

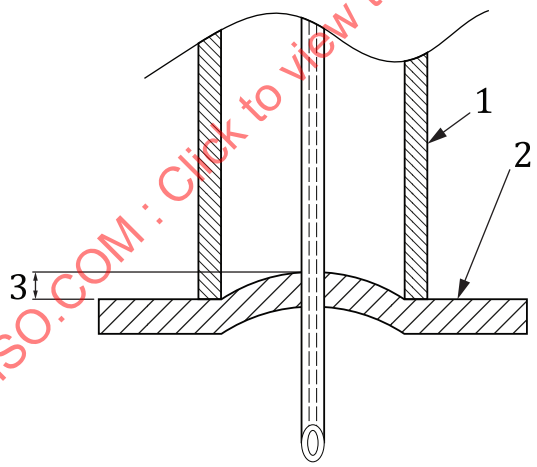
C.1 General

C.1.1 Intended injection depth

Intended injection depth is the range of distance from the skin surface to the point at which the medicinal product should be delivered. This is a specification for the depth at which the medicinal product should be delivered and is not a feature of the injection device. The device should, however, be designed such that the medicinal product is delivered within the intended injection depth limits. Intended injection depth should take into account factors such as intended route of administration (for example sub-cutaneous or intra-muscular), injection site, and the distribution in the patient population's age, gender and BMI. However, the intended injection depth should be expressed relative to the skin contact surface of the device because this is most useful for device design and verification purposes.

If the NIS-AUTO can cause skin doming or other skin deformation, the intended injection depth should take into consideration the deformation in the skin surface. Figure C.1 illustrates skin doming.

Depending on skin deformation, actual injection depth might need to be adjusted accordingly.



Key

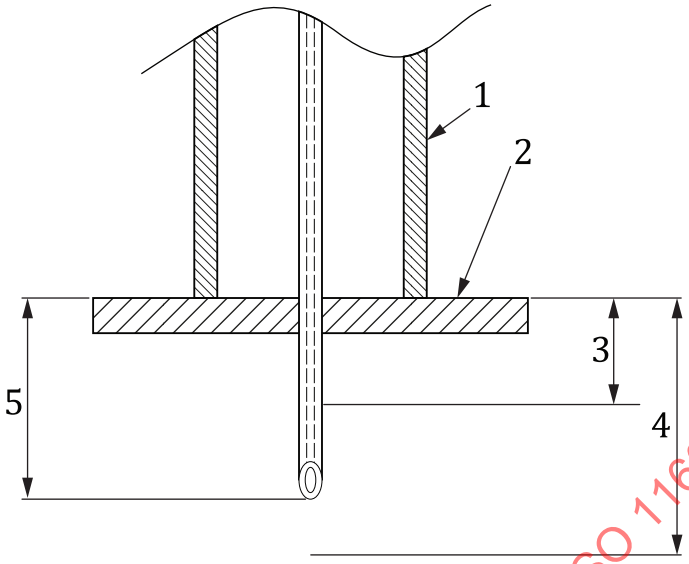
1 NIS-AUTO
2 skin surface
3 skin deformation (shown as doming here)

Figure C.1 — Intended injection depth and skin doming

C.1.2 Needle extension

Needle extension is the distance, as measured, by which the tip of the needle protrudes from the part of the NIS-AUTO in contact with the skin at the injection site. Where the needle does not protrude perpendicular to the skin contact surface, needle extension should still be measured perpendicular to the skin contact surface. This is a feature of the NIS-AUTO and can be used in determination of whether or not the device delivers the medicinal product at the intended injection depth.

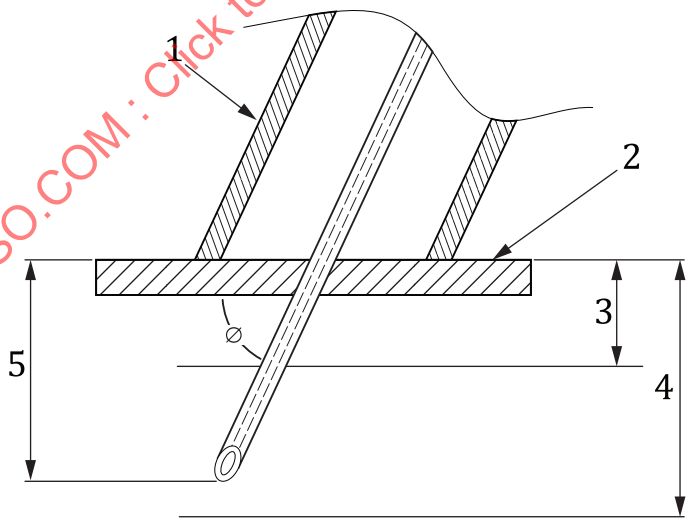
Figures C.2 and C.3 illustrates needle extension at 90° and at less than 90°.



Key

1 NIS
2 skin surface
3 minimum intended injection depth
4 maximum intended injection depth
5 needle extension

Figure C.2 — Intended injection depth and needle extension – 90° insertion



Key

1 NIS
2 skin surface
3 minimum intended injection depth
4 maximum intended injection depth
5 needle extension

Figure C.3 — Intended injection depth and needle extension – ø < 90° insertion

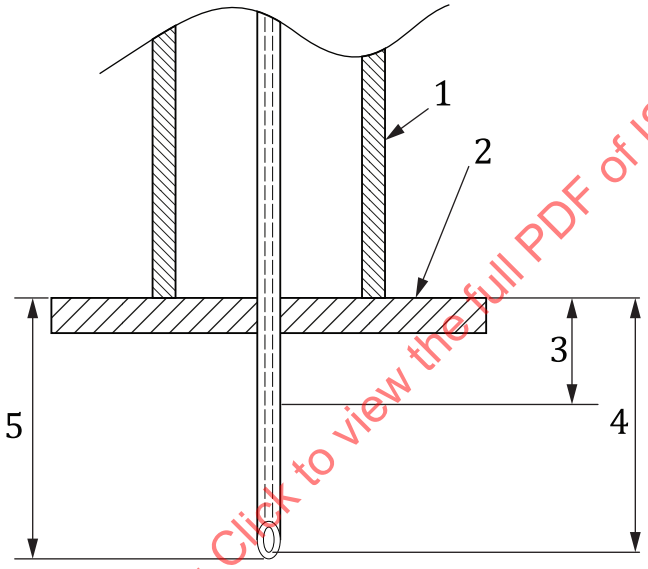
C.2 Test method for determination of injection depth of conventional needles

C.2.1 General

The intended injection depth should be determined to demonstrate that the required dose of medicinal product will be delivered between the minimum and maximum limits of the intended injection depth.

C.2.2 Maximum intended injection depth

For needles with a conventional orifice near to the tip it should be acceptable to use the needle extension as the maximum intended injection depth limit because the position of the distal edge of the needle orifice, which is the furthest point from the skin surface at which medicinal product will be delivered, is always nearer to the skin surface than the needle tip. Therefore, if the needle extension is less than or equal to the specified maximum intended injection depth the NIS-AUTO fulfils the requirement specified in 4.8. This is illustrated in Figure C.4.



Key

1 NIS
2 skin surface
3 minimum intended injection depth
4 maximum intended injection depth
5 needle extension

Figure C.4 — Distal edge of needle orifice at maximum intended injection depth

The needle extension shown in Figure C.4 (key item 5) is slightly more than the maximum intended injection depth. The orifice edge does not extend beyond the maximum intended delivery depth, so no medicinal product can be delivered beyond that depth. If there is a large bevel angle or the medicinal product is delivered only by a radial orifice or side port, the needle extension may be greater than the maximum intended injection depth. The offset between the maximum intended injection depth and the maximum permitted needle extension should be determined based on a tolerance analysis of the bevel geometry or orifice location. However, the maximum permissible needle extension might also be limited by other factors, such as the risk of striking bone, if the offset is large.

C.2.3 Minimum intended injection depth

Determination of the minimum injection depth can be performed by dose accuracy measurement obtained using a test set-up as specified in Annex B, where medicinal product delivered outside of the minimum injection depth is excluded, or by other methods that demonstrate that the specified dose