INTERNATIONAL STANDARD

ISO 11608-2

Second edition
2012-04-01

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

Part 2: Needles

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

Partie 2: Aiguilles

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 11608-2 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.

This second edition cancels and replaces the first edition (ISO 11608-2:2000), which has been technically revised.

ISO 11608 consists of the following parts, under the general title *Needle-based injection systems for medical use — Requirements and test methods*:

— *Part 1: Needle-based injection systems*

— *Part 2: Needles*

— *Part 3: Finished containers*

— *Part 4: Requirements and test methods for electronic and electromechanical pen-injectors*

— *Part 5: Automated functions*

Introduction

This part of ISO 11608 covers sterile double-ended needles intended for single use in conjunction with needle-based injection systems (e.g. pen injectors). These needles are often referred to as pen needles.

The devices described in this part of ISO 11608 are designed to be used with the devices described in ISO 11608-1 and ISO 11608-3.

The first edition of this part of ISO 11608 introduced the concept of interchangeability and the labelling designations “Type A” (i.e.interchangeable) and “non-Type A” for needles and container closure systems. Since its promulgation, experience has shown that the complexity of these systems makes it very difficult to ensure functional compatibility as defined in the different parts of this International Standard, particularly when products are made by different manufacturers and the design is not verified as a system. Based on this experience, it is believed that the Type A designation does not represent adequate guidance to the user in making decisions on the compatibility of needles and container closures with specific needle-based injection systems (NIS). As such, the labelling designation “Type A” has been removed.

This second edition of ISO 11608-2 addresses functional compatibility of the system through testing in accordance with Clause 11. Flow rate is introduced as a new parameter. The sampling plans for inspection selected for this part of ISO 11608 are intended to verify, at a high confidence level, the manufacturer’s ability to manufacture one “lot” of needles that conforms to the critical product attributes. The sampling plans for inspection do not replace the more general manufacturing quality systems that appear in standards on quality systems, for example ISO 9000.

This part of ISO 11608 does not specify requirements or test methods for freedom from biological hazards because no international agreement on the methodology and the pass/fail criteria has been reached. Guidance on biological tests relevant to double-ended needles is given in ISO 10993-1, and it is suggested that manufacturers take this guidance into account when evaluating products. Such evaluation should include the effects of the sterilization process. However, national regulations might exist in some countries, which might take precedence over the guidance in ISO 10993-1.

In some countries, national regulations exist and their requirements might supersede or complement this part of ISO 11608.

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

Part 2: Needles

1 Scope

This part of ISO 11608 specifies requirements and test methods for single-use, double-ended, sterile needles for needle-based injection systems (NISs) that fulfil the specifications of ISO 11608-1.

It is not applicable to:

— needles for dental use;

— pre-filled syringe needles;

— needles pre-assembled by the manufacturer;

— needles not requiring assembly or attachment to the NIS.

2 Normative references

The following referenced documents are indispensable for the application 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 7864:1993, *Sterile hypodermic needles for single use*

ISO 9626, *Stainless steel needle tubing for the manufacture of medical devices*

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

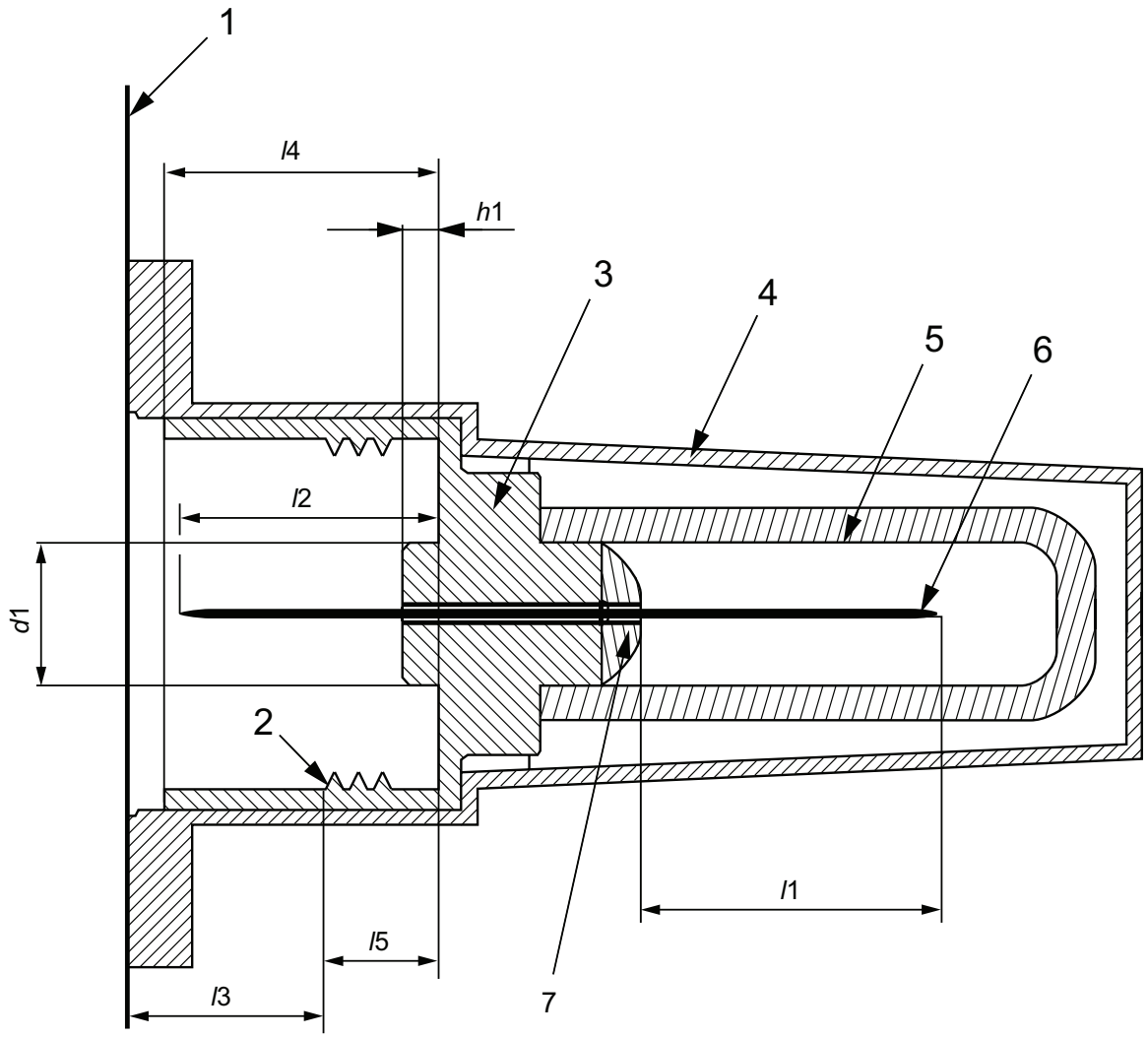
IEC 60068-2-30:2005, *Environmental testing — Part 2-30: Tests — Test Db: Damp heat, cyclic (12 h + 12 h cycle)*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
NIS
needle-based injection system
system intended for parenteral administration by injection of medicinal products using a multi-dose or single-dose container

See Figure 1.



Key

1 seal
2 means of needle assembly attachment
3 needle hub
4 needle container
5 needle shield (not required)
6 needle tube
7 jointing medium (if used)

NOTE The needle container may serve as a needle shield.

Figure 1 — Example presentation of needle assembly for a NIS

3.2
seal
removable barrier which is intended to maintain the sterility of the needle inside the needle container

3.3
unit packaging
needle container, together with the seal forming the packaging of the device, that maintains the sterility of the needle

3.4
user packaging
what is provided to the user with one or a collection of devices, in their unit packaging, of the same item and from the same manufacturing batch

4 Requirements

4.1 Materials

The needle shall be made of tubing materials specified in ISO 9626 or ISO 15510. The requirements in ISO 9626 apply.

4.2 Dimensions

4.2.1 General

The dimensions of the needle assembly attachment part shall be such that the needle fits and functions with NISs that meet the requirements specified in 11608-1.

The tubing characteristics used in needles shall meet the requirements of ISO 9626. If the tubing is not covered in that International Standard, the requirements for stiffness and breakage shall be adapted to corresponding requirements for the defined sizes.

4.2.2 Dimensions for needles

Needles shall fit the test apparatus specified in 7.3. Dimensions shall be in accordance with Table 1.

Table 1 — Dimensional requirements of needle assembly

Measurements	Dimensions mm
l_1	specified length ±1,25
l_2	5,7 to 7,0
l_3	<6,0
l_4	<7,5
l_5	<3,7
h_1	0 to 1,0
d_1	0 to 3,0

Needles may be deliberately designed not to fit the test gauge described in 7.3 and not to meet the dimensional requirements given in Table 1. In such cases, a dedicated test gauge for the specific design shall be created in order to perform the test in 4.8. In addition, the remaining requirements, other than those in 4.2.2, shall apply. In cases where the dimensional requirements of 4.2.2 are not met, the labelling shall state that the needle be used exclusively with the NIS designed for, and tested with, this needle.

4.3 Determination of flow rate through the needle

The needle shall be tested in accordance with Annex A to determine the flow rate through the needle, in millilitres per minute. In addition to complying with the labelling requirements of Clause 12, the flow rate shall be made available on request.

NOTE The flow rate parameter is not a strict requirement of Clause 12, but may be of interest for a NIS manufacturer or other party. Flow rate is an important factor in the overall NIS system performance, as is the injection force and injection time.

4.4 Bond between hub and needle tube

The union of the hub and needle tube shall not break when tested in accordance with Clause 9.

4.5 Needle points

When examined under a magnification of ×2,5, needle points shall appear sharp and free from feather edges, burrs and hooks.

The needle point at the cartridge end shall be designed so as to minimize coring and fragmentation when penetrating the cartridge septum.

4.6 Freedom from defects

The needle tube shall fulfil the requirements of ISO 7864:1993, 11.3.

4.7 Lubrication

The needle tube shall be lubricated at both the patient end and the cartridge end. The lubricant shall not, under normal or corrected-to-normal vision, be visible as droplets of fluid on the outside surface of the needle tube.

4.8 Dislocation of measuring point at patient end

Dislocation of the cannula point at the patient end shall be in accordance with Table 2 when tested in accordance with Clause 8.

Table 2 — Maximum allowable dislocation at patient end

Patient-end needle length l_1 mm	Maximum allowable dislocation d_{max} mm
8	0,9
12	1,1
16	1,4
Others	$0,07 \times l_1 + 0,3$

4.9 Determination of functional compatibility with needle-based injection systems

Compatibility with any NIS shall be claimed only after testing in accordance with Clause 11. Functional requirements are also defined in other parts of ISO 11608 and in the instructions for use of the NIS.

4.10 Ease of assembly and disassembly

Attachment of the needle shall be possible without removing the needle from its opened unit packaging. Compliance is checked according to the requirements of Clause 11.

4.11 Sterility

The needle in its unit packaging shall have been subjected to a validated sterilization process.

5 Sampling

Select 350 needles.

Use 50 needles for the first sample test cycle (sample 1). If two or more needles do not meet the test criteria, the needle type in question is rejected. However, the needle type cannot be accepted based on this first sample alone.

If the needle type is not rejected on the first sample test cycle, perform a test cycle incorporating a second sample of 50 needles (sample 2). If three or more needles fail the test, the batch shall be rejected. If no needles fail the test, the needle type is accepted.

If two needles for sample 1 or three needles for sample 2 fail the test, select a third sample of 50 needles and continue down the table, using the acceptance and rejection test criteria shown in Table 3.

Table 3 — Sampling plan and acceptance/rejection criteria

Sample number	Sample size	Cumulative sample size	Acceptance criteria[a]	Rejection criteria[a]
1	50	50	N/A[b]	2
2	50	100	0	3
3	50	150	0	3
4	50	200	1	4
5	50	250	2	4
6	50	300	3	5
7	50	350	4	5

NOTE The numbers in the table are derived from the original version in ISO 2859-1.

[a] Number of needles.

[b] Acceptance not permitted at this stage.

6 Pre-conditioning of needles

6.1 Pre-conditioning in a dry-heat atmosphere

Place the needle within its unit packaging in a test chamber for at least 96 h in the following atmosphere:

— temperature: (70 ± 2) °C;

— relative humidity: (50 ± 10) %RH.

6.2 Pre-conditioning in a cold-storage atmosphere

Place the needle within its unit packaging in a test chamber for at least 96 h in the following atmosphere:

— temperature: (−40 ± 3) °C.

6.3 Pre-conditioning in a cyclical atmosphere

Place the needle within its unit packaging in a test chamber. Carry out conditioning in accordance with IEC 60068-2-30 as follows:

— variant 1 [see IEC 60068-2-30:2005, Figure 2 a)];

— lower temperature: (25 ± 3) °C (no humidity requirement);

— upper temperature: (55 ± 2) °C;

— six cycles.

NOTE The relevant clauses of IEC 60068-2-30:2005 are Clause 4 (testing chamber), Clause 7 (conditioning) and Clause 9 (recovery).

7 Standard atmosphere and apparatus for tests

7.1 General

Any suitable test system can be used provided that the required accuracy (calibration) and precision (Gauge R&R) can be obtained. The repeatability and reproducibility (Gauge R&R) of the test apparatus shall not exceed 20 % of the allowed tolerance range for any given measurement. For destructive test measurements, the Gauge R&R shall not exceed 30 % of the allowed tolerance range. At a minimum, the Gauge R&R should cover ±2 standard deviations (thereby covering approximately 95 % of the variation).

EXAMPLE A measurement system with a measurement specification limit of ±0,01 ml (range of 0,02 ml) comes out of the Gauge R&R with a Gauge R&R to tolerance range ratio of 20 %, which means that the Gauge R&R (four standard uncertainties) equals 0,02 ml/5 ml = 0,004 ml. The uncertainty of the measurement is ±2 standard deviations (see ISO Guide 98-1), which equals 0,002 ml.

Some of the requirements in this part of ISO 11608 only have one-sided limits, in which case the Gauge R&R should only be used to find the R&R standard deviation. The measurement uncertainties are calculated as twice the Gauge R&R standard deviations.

For such measurements in this part of ISO 11608, the maximum measurement uncertainty requirements are:

— 0,01 mm for dimensions;

— 0,001 Nm for torques;

— 0,001 bar for pressures;

— 0,25 s for time;

— 0,001 g for mass.

All doses, V, delivered are recorded gravimetrically, m (expressed in grams). These recordings are converted to volumes, m, by using the density, ρ, (expressed in grams per millilitre) for the test liquid at environmental conditions. The following equation can be used to convert gravimetric measurements to volumetric:

$$V_{\text{meas}} = \frac{m}{\rho}$$

7.2 Standard test atmosphere

Unless otherwise specified, measurements shall be performed in the following atmosphere:

— temperature from 18 °C to 28 °C,

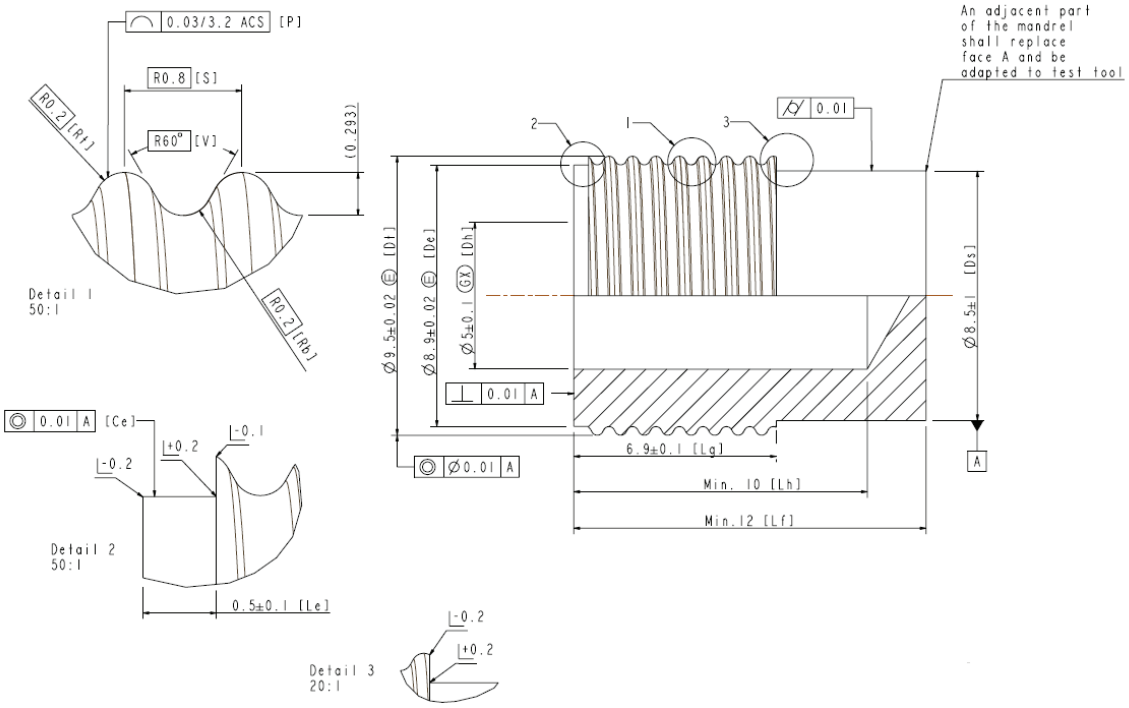
— relative humidity from 25 %RH to 75 %RH,

after having been subjected to storage for at least 4 h in this atmosphere.

7.3 Test gauge

The test gauge shall be made out of hardened steel, e.g. W1.803. The dimensions shall be in accordance with Figure 2.

Dimensions in millimetres



[a] An adjacent part of the mandrel shall replace face A and be adapted to the test tool.

Figure 2 — Test gauge for needles

Needles may be deliberately designed not to fit the test gauge shown in Figure 2 and not to meet the dimensional requirements given in Table 1.

8 Determination of dislocation of measuring point at patient end

Select samples in accordance with Clause 5.

Tighten the needle to the test gauge (see Figure 2) with a torque of (0,07 ± 0,01) Nm.

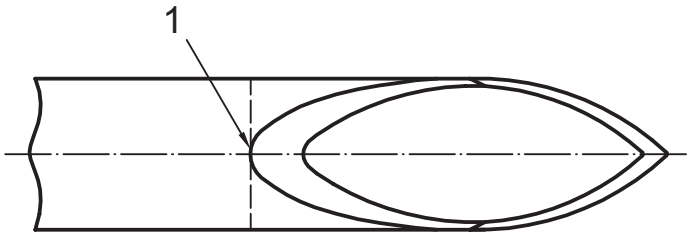
Place the test gauge upon a “V-block” that is affixed to the cross-slide of an optical comparator.

Align the top edge of the cylindrical part of the test gauge outer diameter with the x-axis of the comparator.

Move the “V-block” upwards by half the outer diameter of the test gauge. This will align the test gauge centre line with the x-axis of the comparator.

Rotate the test gauge by hand and record the maximum dislocation (positive or negative) of the centre of the lumen at the level of the measuring point shown in Figure 3 relative to the x-axis of the comparator.

NOTE Methods other than the non-contact method are acceptable to determine dislocation.



Key

1 measuring point

Figure 3 — Point on the needle for measuring dislocation

9 Bond between hub and needle tube

Select samples in accordance with Clause 5.

Attach the needle with a torque of (0,07 ± 0,01) Nm to the test gauge (see Figure 2) or to each NIS for which it is intended. In both cases, the needle shall be attached in accordance with the instructions for use. Verify that the needle is completely attached.

Pull the needle tube with the appropriate force specified in ISO 7864, applied at the patient end of the needle. Pull in the direction of the test gauge or the pen-injector axis for 5 s.

Repeat the test with new needles after pre-conditioning the needles in accordance with 6.1, 6.2 and 6.3.

10 Packaging

Each needle shall be sealed in its unit packaging. One or more unit packages shall be contained in the user packaging.

The materials used in the unit packaging shall not have a detrimental effect on the contents. The materials and design of this container should ensure:

a) maintenance of the sterility of the contents under normal handling and storage;

b) minimal risk of contamination of the contents during removal from the container;

c) that when the seal is removed there is no interference with the subsequent assembly of the needle and NIS;

d) adequate protection of the contents during normal handling, transit and storage;

e) that the container cannot be resealed once it has been opened and that there is evidence of the container having been opened.

11 Test method for validating the compatibility of needles and injector systems

11.1 Principle

A specified torque is applied in order to attach the needle to the NIS. After resting for at least 10 s, the clinically relevant fluid pathway is confirmed for integrity via dose testing (at V_{high} and V_{low} settings of the NIS where $V_{low} \leq 10$ % of the NIS maximum dosage and $V_{high} \geq 90$ % of the NIS maximum dosage).

Finally, the needle hub removal torque is measured and recorded.

11.2 Apparatus and equipment

11.2.1 Torque testing apparatus, capable of holding the needle and the NIS firmly (for needles with a thread). The apparatus shall be capable of applying an assembly torque (clockwise direction) of (0,07 ± 0,01) Nm, with a resolution of ±0,001 Nm. The apparatus shall also be capable of applying a removal torque (anti-clockwise direction) and recording the peak value result. If the needle has no thread, applicable assembly and disassembly testing shall be adapted to the corresponding requirements.

11.2.2 Timer, capable of timing 10 s with a resolution of ±1 s.

11.2.3 Dose accuracy apparatus, capable of capturing and weighing fluid as it is dispensed from the tested NIS, with a resolution of 0,000 1 g. This should include a laboratory scale/balance with draft guards and weigh pans (for further information on determination of dose accuracy, see ISO 11608-1).

11.3 Sample quantity requirements

11.3.1 The test needle samples shall be chosen taking into consideration the requirements given in 11.3.2 to 11.3.5.

11.3.2 Dose accuracy is evaluated by delivering and measuring combinations of injection cycles (in random sequence) of two pre-determined doses (together known as a replicate).

11.3.3 A test replicate includes two dose levels, where $V_{low} \leq 10$ % of the NIS maximum dosage and $V_{high} \geq 90$ % of the NIS maximum dosage.

11.3.4 For variable-dose NISs, the test sample requirement is 60 ($n = 60$) measurements at each dose level, using a new needle for each of the high-dose and low-dose deliveries. Therefore, this test method requires a total of $n = 120$ needles to obtain the dose results for each NIS tested. For fixed-dose NISs, a total of $n = 60$ is required at the fixed-dose level, using a new needle for each test. For single-use NISs, a total of $n = 60$ is required at the dose level, using a new needle for each test.

11.3.5 The same $n = 120$ needles used for the dose accuracy testing shall be used for the needle hub removal torque testing.

The actual drug product, or a fluid yielding similar results to the drug product, may be used for testing.

11.4 Procedure

11.4.1 Needle hub — Assembly

NOTE This is a prerequisite for the torque removal test.

11.4.1.1 Select 120 needles and an adequate supply of the NIS to be tested. The number of needles should be calculated prior to testing. The NIS fluid volume and the maximum NIS dosage are some of the factors that determine this required quantity.

If required by the acceptance criteria and test results, additional needles and NISs may also need to be prepared and tested.

11.4.1.2 Load the associated cartridge into the reusable NIS, as applicable. For needle-based injection devices with integrated non-replaceable containers, the fluid is within the NIS itself and no cartridges are used.

11.4.1.3 Prime the NIS, as needed, with a spare needle until a stream of fluid has been dispensed. This is to ensure that the drive component of the NIS contacts the stopper, i.e. the NIS is primed. Remove the spare needle.

11.4.1.4 Insert the NIS into the needle hub torque test apparatus.

11.4.1.5 Attach a test needle onto the NIS with an application torque of (0,07 ± 0,01) Nm. Record the peak assembly (torque-on) measured results.

11.4.1.6 Start the 10 s timer. Allow the assembly to rest for at least 10 s. Carefully remove the pen from the torque tester.

11.4.2 Needle dose accuracy

11.4.2.1 Dose accuracy can be measured with the needle submerged or non-submerged, with the measurement equipment meeting the Gauge R&R criteria specified in Clause 7.

11.4.2.2 Prepare the balance or measurement equipment.

11.4.2.3 Prime the NIS (if not already primed) according to the manufacturer's instructions for use.

11.4.2.4 Select and set the first target dose on the NIS. This is the V_{low} or the V_{high} dose according to a random or alternating dosing sequence.

11.4.2.5 Tare the balance.

11.4.2.6 Deliver and maintain pressure on the NIS actuator to dispense the liquid dose to the measurement equipment.

11.4.2.7 Deliver the dose according to the manufacturer's instructions for use.

11.4.2.8 Allow the mass on the balance/measurement equipment to stabilize. Observe and record the first stable mass within 5 s after the specified hold time given in the instructions for use has elapsed.

Be sure to tare the scale just before each dose delivery. When a new weigh pan is needed, add a small pool of fluid, place it on the scale and tare the scale.

11.4.3 Needle hub torque removal

11.4.3.1 Carefully replace the NIS in the torque testing device, unscrew the pen needle threaded hub from the NIS test gauge described in 7.3, and record the peak (torque-off) removal torque result.

11.4.3.2 Repeat the above procedure (from 11.4.1.5) for the second target dose on the NIS with a new needle. This is the other dose (either the V_{low} or the V_{high}) according to a random or alternating dosing sequence.

11.4.3.3 Repeat the above procedure (from 11.4.1.5) to complete the other required test replicates using the same pen and cartridge (needle-based injection device with replaceable container) or a needle-based injection device with integrated non-replaceable container, as required by the NIS fluid volume size.

11.4.4 Repeating the tests with a replacement NIS

11.4.4.1 A NIS with an integrated non-replaceable container or with an integrated replaceable container should be used until the fluid is depleted in accordance with typical NIS usage guidelines, i.e. the next required full dose cannot be set and/or delivered.

11.4.4.2 When required by the remaining low fluid volume, use a new NIS with an integrated non-replaceable container, or insert a new cartridge (and cartridge holder, if threaded) into a new NIS with replaceable container, as applicable.

11.4.4.3 Repeat the steps from 11.4.1.5 until all 120 (60 for fixed-dose NISs) needles have been tested. Follow a test schedule (random or alternating high and low settings) for all the required NISs with replacement containers (or NISs with integrated non-replaceable containers) and sample pen needles being tested. Convert all mass readings to volume, using the appropriate density for the test liquid and environmental conditions.

11.5 Acceptance criteria

11.5.1 The needle assembly torque values shall all be within the range of 0,060 Nm to 0,080 Nm.

11.5.2 For doses ≤ 0,20 ml, the dose test is considered acceptable if the calculated values (of the collected dispensed fluid doses) are within ±0,01 ml of the targeted dose.

Using the k factor corresponding to the sample size (i.e. $n = 60$, $k = 2{,}67$ for 95 % confidence and 97,5 % reliability), the following two conditions shall be met:

$$\bar{S} + (k \times S_{\mathrm{sd}}) \leq UL$$

and

$$\bar{S} - (k \times S_{\mathrm{sd}}) \geq LL$$

where

$\bar{S}$ is sample mean;

S_{sd} is sample standard deviation;

UL is upper specification limit;

LL is lower specification limit.

11.5.3 For doses > 0,20 ml, the dose test is considered acceptable if the calculated values (of the collected dispensed fluid doses) are within ±5 % of the targeted dose.

Using the k factor corresponding to the sample size (i.e. $n = 60$, $k = 2{,}67$ for 95 % confidence and 97,5 % reliability), the following two conditions shall be met:

$$\bar{S} + (k \times S_{\mathrm{sd}}) \leq UL$$

and

$$\bar{S} - (k \times S_{\mathrm{sd}}) \geq LL$$

where

$\bar{S}$ is sample mean;

S_{sd} is sample standard deviation;

UL is upper specification limit;

LL is lower specification limit.

11.5.4 The needle hub removal torque shall be less than 0,100 Nm. If the needle has no thread, applicable assembly and disassembly testing shall be adapted to the corresponding requirements.

11.5.4.1 If three or more needles result in a peak (removal) torque of 0,100 Nm or more, the test is rejected.

11.5.4.2 If zero, one or two needles result in a peak (removal) torque of 0,100 Nm or more, the test results are accepted.

11.6 Test report

The test report shall contain at least the following information:

a) date(s) of testing;

b) identity of the NIS tested;

c) identity of the needles tested;

d) identity of the apparatus/equipment used for testing;

e) identification of the test fluid/liquid/drug used for testing;

f) temperature and relative humidity of the testing environment;

g) measured results of the testing, including the needle hub removal torque and the dose accuracy data.

12 Information supplied by the manufacturer

12.1 General

The needle shall be accompanied by information that is sufficient for its safe use, taking into account the training and knowledge of potential users. The information shall include the identity of the manufacturer.

Instructions for use shall be included in the user packaging, unless the needles can be used safely without any such instructions.

The flow rate, determined in accordance with 4.3, should be made available with the labelling.

12.2 Marking

12.2.1 General

Any marking on the unit packaging that is essential for the safe use of the NIS shall be visible and easily legible.

12.2.2 Marking on the unit packaging

The marking on the unit packaging shall comprise at least the following particulars:

a) name of manufacturer or trade name;

NOTE A trademark or logo might be sufficient to identify the manufacturer.

b) details necessary for the user to identify the needle, including the designated metric size, in accordance with the following expression:

o.d. × *l*

where

o.d. is the nominal outside diameter of the needle tube, expressed in millimetres;

l is the nominal length of the needle tube, expressed in millimetres;

EXAMPLE 0,33 mm × 12,7 mm.

c) the word “sterile” or the symbol ISO 7000-2499;

d) batch code or lot number;

e) expiry date, if required (year and month, expressed as YYYY-MM);

EXAMPLE 2009-12.

If it is not possible to mark the expiry date on the unit packaging, it shall appear on the user packaging.

12.2.3 Marking on the user packaging

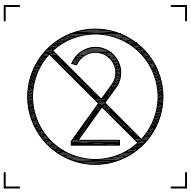
The marking on the user packaging shall comprise at least the following particulars:

a) name and address of the manufacturer;

b) details necessary for the user to identify the needle, including the designated metric size, in accordance with 12.2.2;

c) information on the NISs with which the needle assembly is intended to be used and which have been confirmed as functionally compatible with the needle in accordance with 4.4 (to claim compatibility with any NIS, compatibility shall have been tested in accordance with Clause 11);

d) the words “for single use” or the symbol ISO 7000-1051;



e) the word “sterile” or the appropriate symbol [see 12.2.2 c)];

f) batch code or lot number;

g) expiry date, if required (year and month, expressed for instance as YYYY-MM;

EXAMPLE 2009-12.

h) any special storage and/or handling conditions.

12.3 Instructions for use

The instructions for use, where given, shall contain at least the following particulars:

a) the information required in 12.2.3, except for the information regarding lot number, batch code and expiry date;

b) details of all NISs with which the needle is intended to be used and which have been confirmed as functionally compatible with the needle in accordance with 4.4 (to claim compatibility with any NIS, compatibility shall have been tested in accordance with Clause 11);

c) information on the attachment of the needle to the NIS, if the attachment procedure differs from that given in the instructions for use of the NIS.

Annex A
(normative)

Determination of flow rate through needle

A.1 Principle

The water flow through a sample needle is measured using an appropriate calibrated and qualified flow meter, or an apparatus such as the one outlined in Figure A.1, combined with a calibrated scale.

A.2 Reagent

A.2.1 Distilled water.

A.3 Apparatus

A.3.1 Test fixture, upon which the sample needle is mounted.

A.3.2 Water tank, to which the test fixture is connected, pressurized to (1,1 ± 0,01) bar using compressed air.

NOTE The pressure 1,1 bar is considered to best mimic the average user situation.

A.4 Test procedure

Fill the water tank with water at (23 ± 2) °C and connect or screw the test needle into the test fixture that is connected to the water tank.

The water flows through the needle for at least (15 ± 0,25) s and the efflux is collected in a suitable vessel.

The volume is then determined by weighing, assuming that the density of water equals 1,000 g/ml.

NOTE The tolerances on temperature, pressure and time keeping have been chosen taking into account what is commonly achieved, although it is recognised that they contribute differently to the overall tolerance.

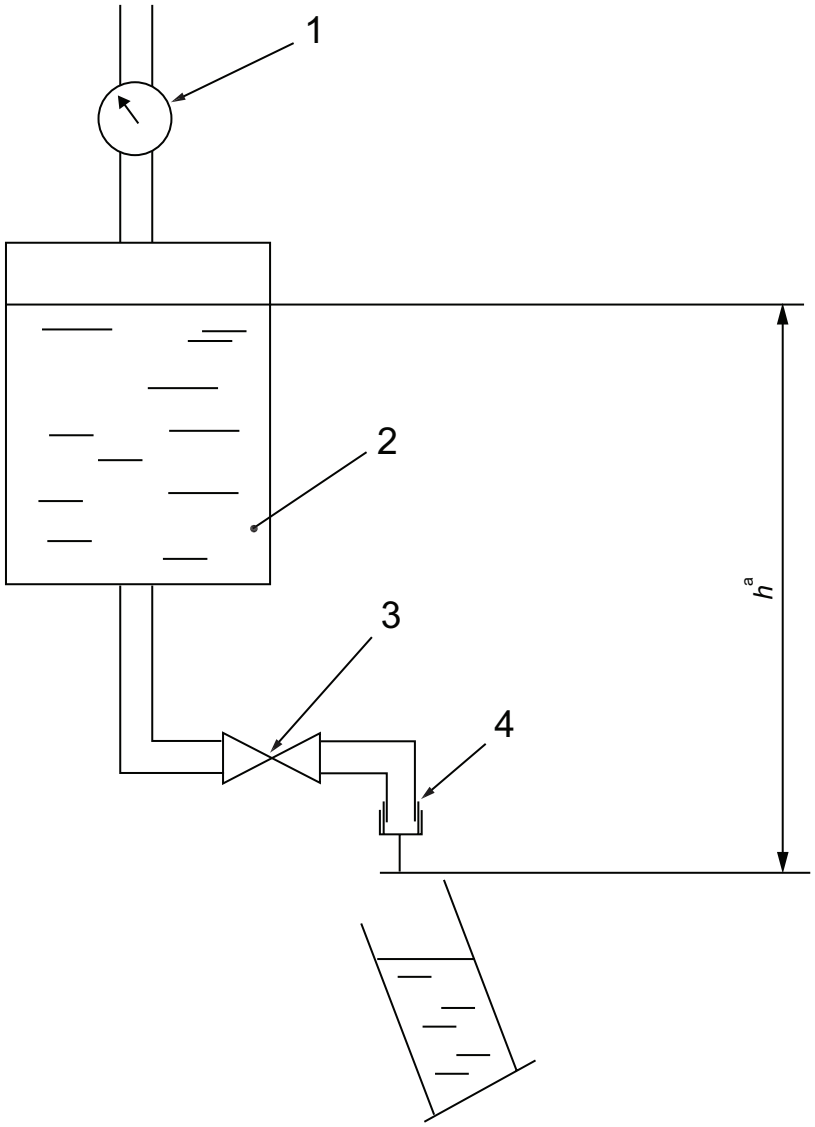
One test run contains 20 sample needles from three batches.

A.5 Test analysis

Calculate the minimum flow rate expected through the needle, in millilitres per minute. Calculate the arithmetic average and standard deviation for the determinations of one test run and define the statistical tolerance interval.

In order to calculate the water flow rate through the needle, use the confidence level of 0,95 (95 %) and the probability level of 0,95 (95 %) to express the one-sided statistical tolerance interval.

Water temperature in the flow path shall not reach more than 25 °C.



Key

1 pressure gauge
2 distilled water
3 ON/OFF valve
4 needle interface

[a] Maximum 100 mm.

Figure A.1 — Example of test equipment

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