INTERNATIONAL STANDARD

ISO 8537

Second edition
2007-10-01

Sterile single-use syringes, with or without needle, for insulin

Seringues à insuline, stériles, non réutilisables, avec ou sans aiguille

Reference number
ISO 8537:2007(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web 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.

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 8537 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 8537:1991) and its Amendment 1 (ISO 8537:1991/Amd.1:2000), which have been technically revised.

Introduction

This International Standard deals with products primarily intended for use with humans and provides performance requirements, but permits some variations of design and of the methods of packaging and sterilization by individual manufacturers.

Materials to be used for the construction and lubrication of sterile syringes and needles for single use are not specified as their selection will depend to some extent upon the design, process of manufacture and sterilization method employed by individual manufacturers.

Syringes and needles should be manufactured and sterilized in accordance with recognized national or international codes of good manufacturing practice for medical devices, and should be free from defects affecting appearance, safety and serviceability for their intended use.

Certain grades of polypropylene, polystyrene and styrene/acrylonitrile copolymer have been extensively used for the barrels of sterile syringes for single use. A high quality natural rubber composition is frequently used for the piston, although other materials such as silicone rubber are also used, the surface of the piston being lubricated with polydimethylsiloxane. For 2 ml syringes, high density polyethylene is frequently used for the seal of the two-component design of syringe in combination with a polypropylene barrel containing a fatty acid amide slip additive.

When selecting materials, make the following considerations:

— Clarity of barrel: Materials used in the construction of the wall of the syringe barrel should be of sufficient clarity to enable dosages to be read without difficulty and for air bubbles to be seen.

— Compatibility with insulin preparations: The materials of syringes and needles (including lubricant) and packaging should not, in their final form after sterilization and under conditions of normal use, detrimentally affect the efficacy, safety and acceptability of insulin preparations: neither should the construction materials themselves be affected physically or chemically by insulin preparations.

— Biocompatibility: The materials should not cause the syringes and needles to yield, under conditions of normal use, significant amounts of toxic substances and should permit them to satisfy the appropriate national requirements or regulations for freedom from pyrogenic materials and abnormal toxicity. For testing these properties, an extract as specified in Annex H may be used.

It is strongly recommended that regulatory authorities, pharmacopoeia and relevant trade associations should recognize the need for further testing, especially for incompatibility between the insulins and syringes when they are in contact for prolonged periods.

In some countries national regulations are legally binding and the requirements may take precedence over this International Standard.

This International Standard describes syringes with or without needles for use with 40 units of insulin/ml (U-40) and 100 units of insulin/ml (U-100). It is recommended that syringes graduated for only one strength of insulin be used in each country to avoid accidents. For those countries using more than one strength of insulin, the importance of having individual syringes appropriately graduated for only one strength of insulin as specified in this International Standard is emphasized. Serious problems may result if a syringe is used with a strength of insulin for which it is not designed. If the syringe is used for mixing different types of insulin, it is strongly recommended that the procedure is performed in the same order each time.

Sterile single-use syringes, with or without needle, for insulin

1 Scope

This International Standard specifies requirements and test methods for sterile syringes, with or without needles, solely for the injection of insulin. The syringes are single-use only, primarily for use in humans. It covers syringes for use with 40 units of insulin/ml (U-40) and 100 units of insulin/ml (U-100).

Sterile syringes specified in this International Standard are intended for use soon after filling as they are not suitable for containing insulin over extended periods of time.

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 594-1:1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

ISO 7864:1993, *Sterile hypodermic needles for single use*

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

3 Terms and definitions

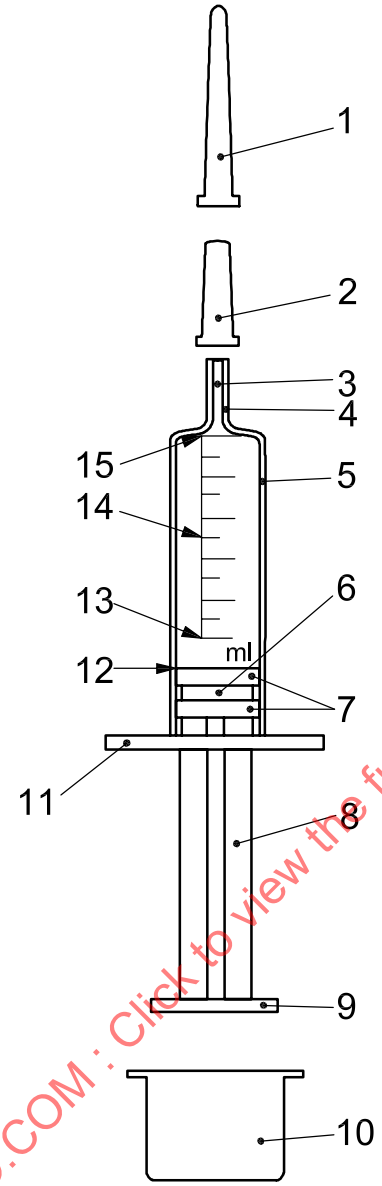
For the purposes of this document the following terms and definitions apply. The nomenclature of some components of syringes for single use is given in Figure 1.

3.1
graduated capacity
volume of water at 20 °C ± 3 °C or 27 °C ± 3 °C expelled from the syringe when the fiducial line on the piston traverses a given scale interval or intervals

3.2
needle cap
protective end cap intended to maintain the sterility of the needle tube and to protect physically the needle tube and needle hub, if present

3.3
needle sheath
cover intended to provide physical protection to the needle tube

3.4
protective end caps
covers intended to enclose the projecting portion of the plunger and push-button at one end and the nozzle and/or the needle at the other end



Key

1	needle cap	9	push-button
2	protective end cap	10	protective end cap
3	nozzle lumen	11	finger grips
4	nozzle	12	fiducial line
5	barrel	13	nominal capacity
6	piston	14	graduation lines
7	seals	15	zero line
8	plunger		

NOTE This figure is intended to be illustrative of components of a syringe only. It does not show a detachable needle or a permanently attached needle tube, and does not form part of the specification. The piston/plunger assembly might or might not be of integral construction and might incorporate more than one seal.

Figure 1 — Schematic representation of insulin syringe for single use

4 Types of syringe

The types of syringe shall be designated as follows in relation to their packaging and combinations with needles:

Type 1: Syringe having a 6 % (Luer) male conical fitting, supplied without a needle and packaged in a unit container.

Type 2: Syringe having a 6 % (Luer) male conical fitting, and supplied without a needle and fitted with protective end caps.

Type 3: Syringe having a 6 % (Luer) male conical fitting, and supplied with a detached or detachable needle and packaged in a unit container.

Type 4: Syringe having a 6 % (Luer) male conical fitting, and supplied with a detachable needle and fitted with protective end caps.

Type 5: Syringe having a fitting other than a 6 % (Luer) taper, supplied with a needle not intended to be detached and packaged in a unit container.

Type 6: Syringe having a fitting other than a 6 % (Luer) taper, supplied with a needle not intended to be detached and fitted with protective caps.

Type 7: Syringe with fixed needle tube and packaged in a unit container.

Type 8: Syringe with fixed needle tube and fitted with protective end caps.

NOTE 1 Eight types are designated to encompass different presentations, but it is likely that the number of types in use in a particular country will be less than eight.

NOTE 2 In addition safety syringes with insulin graduation are available in most markets. At time of publication, a general standard relating to medical sharps prevention features is in development.

5 Freedom from extraneous matter

The surfaces of the syringe and needle, which come in contact with insulin, shall be clean and free from extraneous matter when viewed by normal or corrected vision without magnification.

6 Limits for extraneous matter

6.1 Limits for acidity or alkalinity

The pH value of the extract prepared as described in Annex A shall be determined with a laboratory potentiometric pH meter using a general purpose electrode, and shall be within one pH unit of that of the control fluid.

6.2 Limits for extractable metals

An extract prepared as described in Annex A shall contain not more than a combined total of 5 mg/kg of lead, tin, zinc and iron when tested by a recognized micro-analytical method, for example by an atomic absorption method. The cadmium content of the extract shall be less than 0,1 mg/kg.

7 Lubrication of syringes and needles

If the interior surface of the syringe, including the piston, and the exterior surface of the needle tube are lubricated, the lubricant shall not form pools of fluid on the interior surface of the syringe nor drops on the exterior surface of the needle tube or in the bore.

8 Range of sizes

The range of sizes of syringes and graduations shall be as given in Table 1.

Table 1 — Insulin syringes, range of sizes, graduated scale and tolerance on graduated capacity

Unit scale	Nominal capacity ml	Minimum length of scale mm	Scale interval units	Tolerance on graduated capacity	
				Volumes less than half the nominal capacity	Volumes equal to or greater than half the nominal capacity
	0,3	41	0,5		
U-100	0,3	41	1	± 1 ½ % of the nominal capacity + 2 % of the expelled volume	± 5 % of the expelled volume
	0,5	43	1		
	1,0	57	1		
	1,0	57	2		
U-40	0,5	43	0,5		
	0,5	43	1		
	1,0	50	1		
	2,0	60	1		
	2,0	60	2		

NOTE Syringes having different nominal capacities and scale intervals are designated to encompass different presentations, but the number of types in use in a particular country can be fewer than those given in Table 1.

9 Graduated scale

9.1 Scale

The scale shall be graduated in units of insulin and shall refer to one strength of insulin only. The nominal capacity shall be designated in millilitres (ml).

The tolerances on the graduated capacity shall be in accordance with Table 1.

NOTE The graduated capacity can be conveniently determined by weighing the expelled fluid. See 3.1.

The graduation lines shall be of a uniform thickness between 0,2 mm and 0,4 mm. They shall lie in planes at right angles to the axis of the barrel.

The graduation lines shall be evenly spaced along the longitudinal axis between the zero line and the line for the total graduated capacity.

When the syringe is held vertically, the ends of all graduation lines of similar length shall be vertically beneath each other with a tolerance of ± 0,5 mm.

The length of the short graduation lines shall be approximately half the length of the long lines.

The scale and scale numbers should be legible and of a colour that contrasts clearly with the syringe.

9.2 Numbering of scale

The graduation lines shall be numbered at every five units for the 0,3 ml and 0,5 ml syringes and at every 10 units for the 1,0 ml and 2,0 ml syringes.

The minimum height of the figures should be at least 3 mm.

When the syringe is held vertically with the zero line uppermost and with the scale to the front, the numbers shall appear upright on the scale and in a position such that they would be bisected by a prolongation of the graduation lines to which they relate. The numbers shall be close to, but shall not touch, the ends of the graduation lines to which they relate.

10 Barrel

10.1 Dimensions

The barrel length shall be such that the syringe has a usable capacity of at least 10 % more than the nominal capacity or 5 mm of plunger travel beyond the scale marking, whichever is less.

10.2 Finger grips

The open end of the barrel shall be provided with finger grips which shall ensure that the syringe will not roll when it is placed with the scale uppermost on a flat surface inclined at an angle of 10° to the horizontal.

The finger grips shall be free from flash and sharp edges.

Finger grips should be of adequate size, shape and strength for the intended purpose and should enable the syringe to be held securely during use.

11 Piston/plunger assembly

11.1 General

The design of the plunger and push-button of the syringe shall be such that when the barrel is held in one hand the plunger can be depressed by the thumb of that hand. The piston shall not become detached from the plunger during the test described in Annex B.

The projection of the plunger and the configuration of the push-button should be such as to enable the plunger, when in the fully inserted position, to be grasped and drawn back without difficulty.

11.2 Fit of piston in barrel

When the syringe is filled with water and held vertically with first one and then the other end uppermost, the plunger shall not move by reason of its own mass and the mass of the water contained. When a needle is secured to the syringe in accordance with the instructions of the manufacturer, the force required to initiate movement of the plunger to expel water from the syringe shall not exceed 15 N when measured in accordance with Annex C.

The fit of the piston in the barrel should be such that the piston slides smoothly throughout the graduated length of the barrel.

12 Nozzle

12.1 Conical fitting

The male conical fitting of the syringe nozzle on syringe types 1, 2, 3 and 4 shall comply with the requirements of ISO 594-1.

12.2 Position of nozzle on end of barrel

The syringe nozzle shall be situated centrally, i.e. shall be co-axial with the barrel.

13 Needle tubing and needles

13.1 Needles for syringes of types 3 and 4

Needles for syringes of types 3 and 4 shall be in accordance with ISO 7864, except for the dimensions and test parameters which shall be in accordance with Annex D of this International Standard.

13.2 Needle tubing for syringes of types 5, 6 ,7 and 8

Needle tubing for syringes of types 5, 6, 7 and 8 shall be in accordance with ISO 9626, except for the dimensions and test parameters which shall be in accordance with Annex D of this International Standard. The needle point shall be in accordance with ISO 7864.

14 Performance of assembled syringe

14.1 Dead space

When tested in accordance with Annex E, the dead space shall not exceed the limits given in Table 2.

Table 2 — Maximum dead space

Type of syringe	Maximum dead space ml
1 and 2	0,07
3 and 4	0,10
5 and 6	0,02
7 and 8	0,01

14.2 Freedom from leakage at needle

When tested as described in Annex F, there shall be no leakage of water sufficient to form a falling drop within 30 s from the unions listed in F.2.9.

When tested as described in Annex G, there shall be no continued formation of air bubbles from the unions listed in G.2.6.

14.3 Liquid and air leakage past piston

When tested as described in Annex F, there shall be no leakage of water past the piston seal.

When tested as described in Annex B, there shall be no leakage of air past the piston seal, and there shall be no fall in the manometer reading.

15 Packaging

15.1 Unit containers and self-contained syringe units

15.1.1 General

Syringes of types 1, 3, 5 and 7 shall be packed in unit containers and syringes of types 2, 4, 6 and 8 shall be packed as self-contained syringe units.

15.1.2 Unit containers (syringes of types 1, 3, 5 and 7)

The syringe, together with the needle if supplied, shall be sealed individually in a unit container.

For types 3, 5 and 7, the needle shall be supplied with a protective needle sheath.

The needle of type 3 syringes may be packaged in its own container inside the unit container.

The materials and design of the unit container should have no detrimental effects on the contents and should ensure the following:

a) maintenance of sterility of the contents under dry, clean and adequately ventilated storage conditions;

b) minimum risk of contamination of the contents during opening and removal from the container;

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

d) that once opened, the container cannot be easily re-sealed, and it should be obvious that the container has been opened.

15.1.3 Self-contained syringe units (syringes of types 2, 4, 6 and 8)

The syringe shall be fitted with protective end cap.

The materials and design of the syringe unit should ensure

a) maintenance of sterility of the interior of the syringe unit (e.g. the outside surface of the needle, the protruding part of the plunger and its push-button and the fluid path of the syringe, and needle, if fitted) under dry, clean and adequately ventilated conditions;

b) minimum risk of contamination of the contents during opening of the unit;

c) adequate protection of the contents during normal handling, transit and storage.

The syringe or the syringe unit may be provided with a means of indicating that the unit may have been opened previously.

15.2 Multiple unit pack (syringes of types 2, 4, 6 and 8)

Multiple unit packs shall contain not more than 12 syringe units of syringes of types 2, 4, 6 or 8.

The materials and design of the multiple unit pack should ensure

a) minimum risk of contamination of the syringe unit during opening of the pack;

b) adequate protection of the syringe units during normal handling, transit and storage;

c) that once opened, it should be obvious that the multiple pack has been opened.

15.3 Shelf container

A number of unit containers, syringe units, or a number of multiple unit packs shall be packed in a shelf container.

The container should protect the contents during normal handling, transit and storage.

16 Marking

16.1 General

If colour coding is used for indication of the insulin strength, the colour red shall be used for U-40 syringes and the colour orange shall be used for U-100 syringes.

The colours red and orange shall not be used for marking except for marking the strength of insulin.

Colour coding, if used, can be given on the syringe, protective end caps and/or all packaging.

16.2 Syringes

16.2.1 General

The barrels of syringes shall be marked with the following information:

a) appropriate graduated scale in accordance with Clauses 8 and 9;

b) the text “U-40 insulin” or “U-100 insulin” whichever is applicable;

c) the word “units” or “I.U.”;

d) total graduated capacity in millilitres.

16.2.2 Additional marking for self-contained syringe units (syringes of types 2, 4, 6 and 8)

The syringe or unit shall additionally be marked with the following information:

a) the words “for single use” or equivalent (such as symbol for single use, symbol number ISO 7000-1051, see Annex I); the term “disposable” shall not be used;

b) name and/or trade-mark of the manufacturer or supplier.

A warning to check the integrity of the seals of the self-contained syringe unit before use may be given.

All information which appears on the barrel should be marked in such a position as to interfere as little as possible with the reading of the graduated scale.

16.3 Unit containers (syringes of types 1, 3, 5 and 7)

The unit container shall be marked with the following information:

a) the word “sterile” or equivalent; a warning to check the integrity of the unit container before use may be given;

b) the words “for single use” or equivalent (such as symbol for single use, symbol number ISO 7000-1051, see Annex I); the term “disposable” shall not be used;

c) an identification reference to the batch and/or the date of manufacture;

d) the external diameter and length of the needle in millimetres, if included; the gauge size of the needle may also be marked.

The unit container shall also be marked with the following information unless the product bears the information and is visible through the unit container:

e) identity of the contents, including the capacity of the syringe and the strength of insulin to be used;

f) name and/or registered trade-mark of the manufacturer or supplier.

16.4 Multiple unit packs (syringe types 2, 4, 6 and 8)

The multiple unit packs shall be marked with the following information:

a) the words “syringe interior sterile” or equivalent;

b) a warning to check the integrity of the seals of the self-contained syringe units before use, unless this warning is given on the syringe unit;

c) the words “for single use” or equivalent (such as symbol for single use, symbol number ISO 7000-1051, see Annex I). The term “disposable” shall not be used.

d) name and/or trade-mark of the manufacturer or supplier unless the product bears this information and is visible through the multiple unit pack;

e) an identification reference to the batch and/or the date of manufacture;

f) the external diameter and length of the needle in millimetres, if included; the gauge size of the needle may also be marked;

g) identity of the contents, including the capacity of the syringe and the strength of insulin to be used unless the information is visible through the multiple unit pack.

16.5 Shelf containers

The shelf container shall be marked with the following information:

a) the word “sterile” or the words “syringe interior sterile” or equivalent as appropriate to the type of syringe contained;

b) a warning, as appropriate to the type of syringe contained, to check the integrity of the unit containers or of the seals of the self-contained syringe unit before use, unless this warning is given on the unit container or syringe unit;

c) the words “for single use” or equivalent (such as symbol for single use, symbol number ISO 7000-1051, see Annex I). The term “disposable” shall not be used.

d) an identification reference to the batch and date (year and month) of sterilization;

e) name and/or registered trade-mark of the manufacturer or supplier;

f) description of contents.

Annex A
(normative)

Fluid for determination of acidity/alkalinity and extractable metals

Fill 10 sterile syringes, including the needle if supplied, to the nominal capacity with freshly prepared distilled water, and maintain them at 37 °C $^{+3}_{0}$ °C for 8 h. Eject the contents and combine them in a vessel made of borosilicate glass.

Prepare the control fluid by reserving an aliquot of the unused distilled water.

Annex B
(normative)

Test method for air leakage past syringe piston during aspiration

B.1 Procedure

B.1.1 The test shall be conducted using the apparatus illustrated in Figure B.1 in accordance with the following procedure.

B.1.2 Draw into the syringe a volume of recently boiled and cooled water of not less than 25 % of the graduated capacity.

B.1.3 With the nozzle uppermost, withdraw the plunger until the fiducial line is at the maximum graduated capacity and clamp the plunger in this position as illustrated in Figure B.1.

B.1.4 Connect the syringe nozzle to a reference steel female conical fitting as specified in ISO 594-1. If the needle is attached by a method other than the use of a 6 % (Luer) conical fitting, insert the needle into the rubber bung or diaphragm fitted to the female conical fitting.

B.1.5 Switch on the vacuum pump with the air bleed control open.

B.1.6 Adjust the bleed control so that a gradual increase in vacuum is obtained and a manometer reading of 88 kPa[1)] is reached.

B.1.7 Examine the syringe for evidence of air leakage past the piston.

B.1.8 Isolate the syringe and manometer assembly by means of a vacuum-tight valve.

B.1.9 Observe the manometer reading for 60 s and record any fall in reading.

B.1.10 Examine the syringe to determine if the piston becomes detached from the plunger.

B.2 Test report

The following information shall be provided:

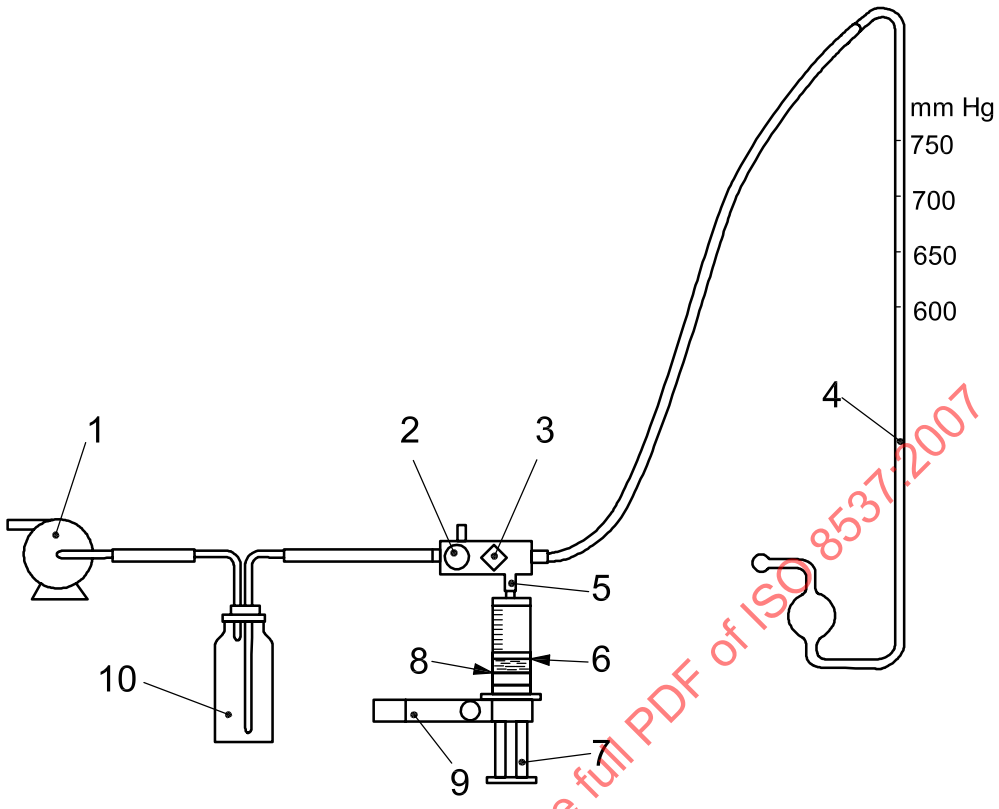
a) the identity of the syringe;

b) the date of testing;

c) a statement as to whether air leakage (as indicated in B.1.7 and B.1.9) was observed;

d) a statement as to whether the piston became detached from the plunger.

1) 1 kPa = 7,5 mm Hg



Key

1	vacuum pump	6	25 % H_2O volume
2	fine bleed control	7	syringe
3	vacuum tight valve	8	nominal capacity
4	manometer	9	clamp
5	ISO 594-1 female conical fitting mount or rubber bung	10	bottle trap

The volume of air enclosed between the syringe tip and the manometer should be as small as possible.

NOTE The apparatus can be used for all types of syringes, as the apparatus can be fitted with either a female conical fitting or a rubber bung.

Figure B.1 — Apparatus used in aspiration tests

Annex C
(normative)

Test method for force required to operate plunger

C.1 Procedure

C.1.1 Apply the needle onto the syringe if not fitted. Syringes of types 1 and 2 shall be fitted with a needle of external diameter of 0,40 mm.

C.1.2 Fill the syringe with water to 50 % of its indicated capacity.

C.1.3 Clamp the syringe onto a suitable test stand with the needle pointing downward.

C.1.4 Wipe away any water from the needle point.

C.1.5 Immediately apply a vertical downward force to the plunger by means of a force gauge and gradually increase the force until the plunger begins to move, the initiation of movement being indicated by the expulsion of water from the needle.

C.1.6 Maintain a force sufficient to sustain the plunger movement until it is fully depressed.

C.1.7 Record the maximum force required to operate the plunger during the test.

C.2 Test report

The following information shall be provided:

a) the identity of the syringe;

b) the date of testing;

c) the force required to initiate movement of the plunger, expressed in newtons.

Annex D
(normative)

Properties of needles and needle tubing

D.1 The diameters of needle tubing shall be in accordance with Table D.1.

Table D.1 — Diameter of needle tubing

Dimensions in millimetres

Nominal outside diameter[a]	Outside diameter		Minimum inside diameter
	min.	max.	
0,25	0,254	0,267	0,114
0,30	0,298	0,320	0,133
0,33	0,324	0,351	0,133
0,36	0,349	0,370	0,133
0,40	0,400	0,420	0,184
0,45	0,440	0,470	0,232

[a] The nominal outside diameters correspond to gauge numbers as follows: 0,25 mm (gauge 31), 0,30 mm (gauge 30), 0,33 mm (gauge 29), 0,36 mm (gauge 28), 0,40 mm (gauge 27) and 0,45 mm (gauge 26).

D.2 The stiffness of needle tubing shall be in accordance with Table D.2. when tested as described in ISO 9626.

Table D.2 — Stiffness

Nominal outside diameter	Span mm ± 0,1	Force N ± 0,1	Maximum deflection mm
0,25	3,5	5,5	0,35
0,30	5,0	5,5	0,40
0,33	5,0	5,5	0,32
0,36	5,0	5,5	0,25
0,40	9,5	5,5	0,60
0,45	10,0	6,0	0,56

D.3 The minimum strength of the bond between the hub/syringe and the needle tubing shall be 22 N when tested in accordance with ISO 7864.

D.4 The stylet diameter to test the patency of the lumen as described in ISO 7864 shall be in accordance with Table D.3.

Table D.3 — Size of stylet to test patency of lumen

Dimensions in millimetres

Nominal outside diameter	Diameter of stylet $^{0}_{-0,1}$
0,25	0,08
0,30	0,11
0,33	0,11
0,36	0,11
0,40	0,15
0,45	0,18

D.5 The resistance to breakage shall be assessed in accordance with Table D.4 when tested as described in ISO 9626.

Table D.4 — Resistance to breakage

Dimensions in millimetres

Nominal outside diameter	Distance between rigid supports and application of bending force ± 0,1
0,25	8
0,30	8
0,33	8
0,36	8
0,40	8
0,45	10

Annex E
(normative)

Test method for determination of dead space

E.1 Preparation of samples

E.1.1 Syringes of types 3 and 4

Remove the needle, if fitted, from the syringe and then refit it as follows.

Connect the nozzle of the syringe to the needle hub. Assemble the components by applying an axial force of 27,5 N for 5 s whilst applying a twisting action to a torque value not exceeding 0,1 N·m to give rotations not exceeding 90°.

E.1.2 Syringes of types 1, 2, 5, 6, 7 and 8

No preparation is necessary.

E.2 Procedure

E.2.1 Weigh the empty syringe including needle if appropriate, prepared in accordance with Clause E.1, to the nearest 0,001 g.

E.2.2 Fill the syringe to the total graduated capacity with distilled water at 20 °C ± 3 °C, taking care to expel all air bubbles, especially from the needle if present, and, in the case of syringes without a needle, ensure that the level of the meniscus coincides with the end of the nozzle lumen.

E.2.3 Expel the water by fully depressing the plunger, and wipe dry the outer surface of the syringe.

E.2.4 Reweigh the syringe.

E.3 Calculation of results

Determine the mass of water in grams remaining in the syringe by subtracting the mass of the empty syringe from the mass of the syringe after expulsion of the water. Record this value as the dead space in millilitres, taking the density of water as 1 000 kg/m^3.

E.4 Test report

The following information shall be reported:

a) the identity of the syringe;

b) the date of testing;

c) the dead space volume of the syringe, expressed in millilitres.

Annex F
(normative)

Test method for liquid leakage at syringe piston and syringe nozzle/hub or needle/barrel unions during compression

F.1 Preparation of samples for testing

F.1.1 Testing for leakage past piston

F.1.1.1 General

Prepare samples for testing as given in F.1.1.2 to F.1.1.4.

F.1.1.2 Syringes of types 1 and 2

Connect the syringe nozzle to a reference steel female conical fitting in accordance with ISO 594-1, both components being dry. Assemble the components by applying an axial force of 27,5 N for 5 s whilst applying a twisting action to a torque value not exceeding 0,1 N·m to give rotation not exceeding 90 °.

F.1.1.3 Syringes of types 3 and 4

Remove the needle, if fitted, and connect the syringe nozzle to a reference steel female conical fitting as described in F.1.1.2.

F.1.1.4 Syringes of types 5 and 6

Ensure that the union between the syringe nozzle and the needle hub is firmly assembled and does not leak.

F.1.1.5 Syringes of types 7 and 8

No preparation is necessary.

F.1.2 Testing for leakage at syringe nozzle

F.1.2.1 General

Prepare samples for testing as given in F.1.2.2 to F.1.2.5.

F.1.2.2 Syringes of types 1 and 2

Connect the syringe to a reference steel female conical fitting as described in F.1.1.2.

F.1.2.3 Syringes of types 3 and 4

Remove the needle, if fitted, and connect the syringe nozzle to a reference steel female conical fitting as described in F.1.1.2.

F.1.2.4 Syringes of types 5 and 6

No preparation is necessary.