INTERNATIONAL STANDARD

ISO 7886-1

First edition
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Sterile hypodermic syringes for single use —

Part 1: Syringes for manual use

Seringues hypodermiques stériles, non réutilisables —
Partie 1: Seringues pour utilisation manuelle

Reference number
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Contents

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Annexes

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.

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.

International Standard ISO 7886-1 was prepared by Technical Committee ISO/TC 84, *Medical devices for injections*, Sub-Committee SC 1, *Syringes, needles and intravascular catheters for single use*.

This first edition of ISO 7886-1 cancels and replaces ISO 7886:1984. It was decided to divide the Standard into two parts, ISO 7886-1 retaining essentially the scope of ISO 7886:1984, and ISO 7886-2 (in course of preparation) being applicable to sterile, single-use syringes for use with power-driven syringe pumps. The major differences between this part of ISO 7886 and ISO 7886:1984 are as follows.

a) In order to reflect the demand for syringes of sizes other than those listed in ISO 7886:1984, this part of ISO 7886 does not specify a range of syringe sizes and allows the syringes to be marked with graduations at greater than the nominal capacity.

b) An informative annex on forces required to operate the syringe plunger has been introduced.

c) The tests for toxicity given in ISO 7886:1984 have been replaced by an informative cross-reference to ISO 10993-1.

d) The informative annex on test methods for compatibility between syringes and injection fluids has been revised.

e) This part of ISO 7886 permits the use on package labelling of the ISO symbol for "do not re-use", but continues to require the written word. Manufacturers are encouraged to use the symbol so as to increase familiarity with it among purchasers and users.

ISO 7886 consists of the following parts, under the general title *Sterile hypodermic syringes for single use*:

— *Part 1: Syringes for manual use*

— *Part 2: Syringes for use with syringe pumps*

Annexes A, B, C and D form an integral part of this part of ISO 7886. Annexes E, F, G, H and J are for information only.

Introduction

This part of ISO 7886 does not give requirements or test methods for freedom from biological hazard. Guidance on biological tests relevant to hypodermic syringes is given in ISO 10993-1, and it is suggested that manufacturers take this guidance into account when evaluating products. Such an evaluation should include the effects of the process whereby the syringes are sterilized. However, national regulations may exist in some countries, and these will override the guidance in ISO 10993-1.

Materials to be used for the construction of syringes are not specified as their selection will depend to some extent upon the design, process of manufacture and method of sterilization employed by individual manufacturers. Guidance on some aspects of the selection of materials is given in annex E.

The materials of the syringe should be compatible with injection fluids. If this is not the case, the attention of the user should be drawn to the exception by labelling the primary container. It is not practicable to specify a universally acceptable test method for incompatibility. However, recommended methods are given in annex F. These test methods can be regarded only as a means of indicating compatibility. The only conclusive test is that of an individual injection fluid with a specific syringe.

Manufacturers of pharmaceuticals use solvents in injectable preparations. Such solvents should be tested by the manufacturer of the injectable preparation for any possible incompatibility with the materials frequently used in syringe construction. The types of material that have received wide acceptance are included in annex E. If an incompatibility exists, the injection should be suitably labelled. The impossibility of testing any one injection fluid with all available syringes is recognized and it is strongly recommended that regulatory authorities and relevant trade associations should recognize the problem and take appropriate measures to assist manufacturers.

Hypodermic syringes specified in this part of ISO 7886 are intended for use with hypodermic needles specified in ISO 7864.

This part of ISO 7886 does not cover syringes for the injection of insulin (see ISO 8537).

In some countries, national pharmacopoeia or government regulations are legally binding and their requirements may take precedence over this part of ISO 7886.

Sterile hypodermic syringes for single use —

Part 1:
Syringes for manual use

1 Scope

This part of ISO 7886 specifies requirements for sterile single-use hypodermic syringes made of plastics materials and intended for the aspiration of fluids or for the injection of fluids immediately after filling.

It excludes syringes for use with insulin (see ISO 8537), single-use syringes made of glass, syringes with needles permanently attached, syringes for use with power-driven syringe pumps, syringes pre-filled with the injection by the manufacturer and syringes supplied with the injection as a kit for filling by a pharmacist.

NOTE 1 A second part of ISO 7886 is being prepared to cover syringes for use with power-driven syringe pumps.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 7886. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 7886 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

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

ISO 594-2:1991, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings.*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods.*

ISO 8601:1988, *Data elements and interchange formats — Information interchange — Representation of dates and times.*

3 Definitions

For the purposes of this part of ISO 7886, the following definitions apply.

3.1 nominal capacity: Capacity of the syringe as designated by the manufacturer.

NOTE 2 Examples are 1 ml, 5 ml, 50 ml.

3.2 graduated capacity: Volume of water at (20 ± 5) °C [or, for tropical countries (27 ± 5) °C] expelled from the syringe when the fiducial line on the piston traverses a given scale interval or intervals.

3.3 total graduated capacity: Capacity of the syringe at the graduation line furthest from the zero graduation line.

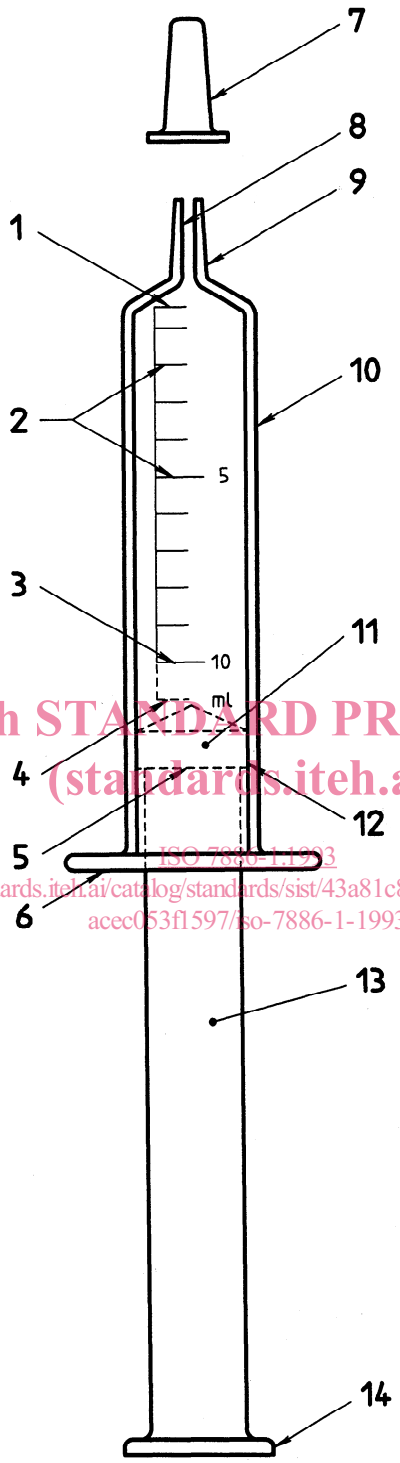
NOTE 3 The total graduated capacity may be equal to, or greater than, the nominal capacity.

3.4 maximum usable capacity: Capacity of the syringe when the piston is drawn back to its furthest functional position.

3.5 fiducial line: Line circumscribing the end of the piston for determining the capacity corresponding to any scale reading of the syringe.

4 Nomenclature

The nomenclature for components of hypodermic syringes for single use is shown in figure 1.



1. Zero graduation line
2. Graduation lines
3. Nominal capacity graduation line
4. Total graduated capacity line
5. Fiducial line
6. Finger grips
7. Nozzle cap
8. Nozzle lumen
9. Nozzle
10. Barrel
11. Piston
12. Seal
13. Plunger
14. Push-button

NOTE — The drawing is intended to be illustrative of components of a syringe. The piston/plunger assembly may or may not be of integral construction and may or may not incorporate more than one seal.

Figure 1 — Schematic representation of hypodermic syringe for single use

5 Cleanliness

When inspected by normal or corrected-to-normal vision without magnification under an illuminance of 300 lx to 700 lx, the surface of the hypodermic syringe which comes in contact with injection fluids during normal use shall be free from particles and extraneous matter.

6 Limits for acidity or alkalinity

When determined with a laboratory pH meter and using a general purpose electrode, the pH value of an extract prepared in accordance with annex A shall be within one unit of pH of that of the control fluid.

7 Limits for extractable metals

When tested by a recognized microanalytical method, for example by an atomic absorption method, an extract prepared in accordance with annex A shall, when corrected for the metals content of the control fluid, contain not greater than a combined total of 5 mg/l of lead, tin, zinc and iron. The cadmium content of the extract shall, when corrected for the cadmium content of the control fluid, be lower than 0,1 mg/l.

8 Lubricant

If the interior surfaces of the syringe, including the piston, are lubricated, the lubricant shall not be visible, under normal or corrected-to-normal vision, as droplets or particles.

An acceptable lubricant, applied undiluted, for three-piece syringes is polydimethylsiloxane complying with a national or the European pharmacopoeia. The quantity of lubricant used should not exceed 0,25 mg per square centimetre of the internal surface area of the syringe barrel.

An acceptable lubricant for two-piece syringes is fatty acid amides of erucic and/or oleic acids. The quantity of lubricant should not exceed 0,6 % (*m/m*) of the mass of the barrel, but attention is drawn to the fact that some national regulations may specify a lower maximum concentration.

9 Tolerance on graduated capacity

The tolerances on the graduated capacity shall be as given in table 1.

Table 1 — Capacity tolerance, dead space, scale dimensions and test forces

Nominal capacity of syringe, V	Tolerance on any graduated capacity		Maximum dead space	Minimum overall length of scale to nominal capacity mark	Scale interval	Increment between graduation lines to be numbered	Forces for leakage testing (see annex D)	
	Less than half nominal capacity	Equal to or greater than half nominal capacity					Side force	Axial pressure (gauge)
							(± 5 %)	(± 5 %)
ml			ml	mm	ml	ml	N	kPa
$V < 2$	± (1,5 % of V + 2 % of expelled volume)	± 5 % of expelled volume	0,07	57	0,05	0,1	0,25	300
$2 \leqslant V < 5$	± (1,5 % of V + 2 % of expelled volume)	± 5 % of expelled volume	0,07	27	0,2	0,5 or 1	1,0	300
$5 \leqslant V < 10$	± (1,5 % of V + 1 % of expelled volume)	± 4 % of expelled volume	0,075	36	0,5	1	2,0	300
$10 \leqslant V < 20$	± (1,5 % of V + 1 % of expelled volume)	± 4 % of expelled volume	0,10	44	1,0	5	3,0	300
$20 \leqslant V < 30$	± (1,5 % of V + 1 % of expelled volume)	± 4 % of expelled volume	0,15	52	2,0	10	3,0	200
$30 \leqslant V < 50$	± (1,5 % of V + 1 % of expelled volume)	± 4 % of expelled volume	0,17	67	2,0	10	3,0	200
$50 \leqslant V$	± (1,5 % of V + 1 % of expelled volume)	± 4 % of expelled volume	0,20	75	5,0	10	3,0	200

10 Graduated scale

10.1 Scale

10.1.1 The syringe shall have either only one scale or more than one identical scales, which shall be graduated at least at the intervals given in table 1. The unit of volume shall be marked on the barrel.

NOTE 4 This requirement does not preclude the provision of additional graduation marks within the scale or as extensions to the scale.

10.1.2 If the scale is extended beyond the nominal capacity, the extended portion shall be differentiated from the rest of the scale.

Examples of means of differentiation are

a) encircling the scale number of the nominal capacity line;

b) the use of smaller scale numbers for the extra graduation lines;

c) the use of shorter graduation lines for the extra graduation lines;

d) the use of a broken line for the optional vertical line of the extra scale length.

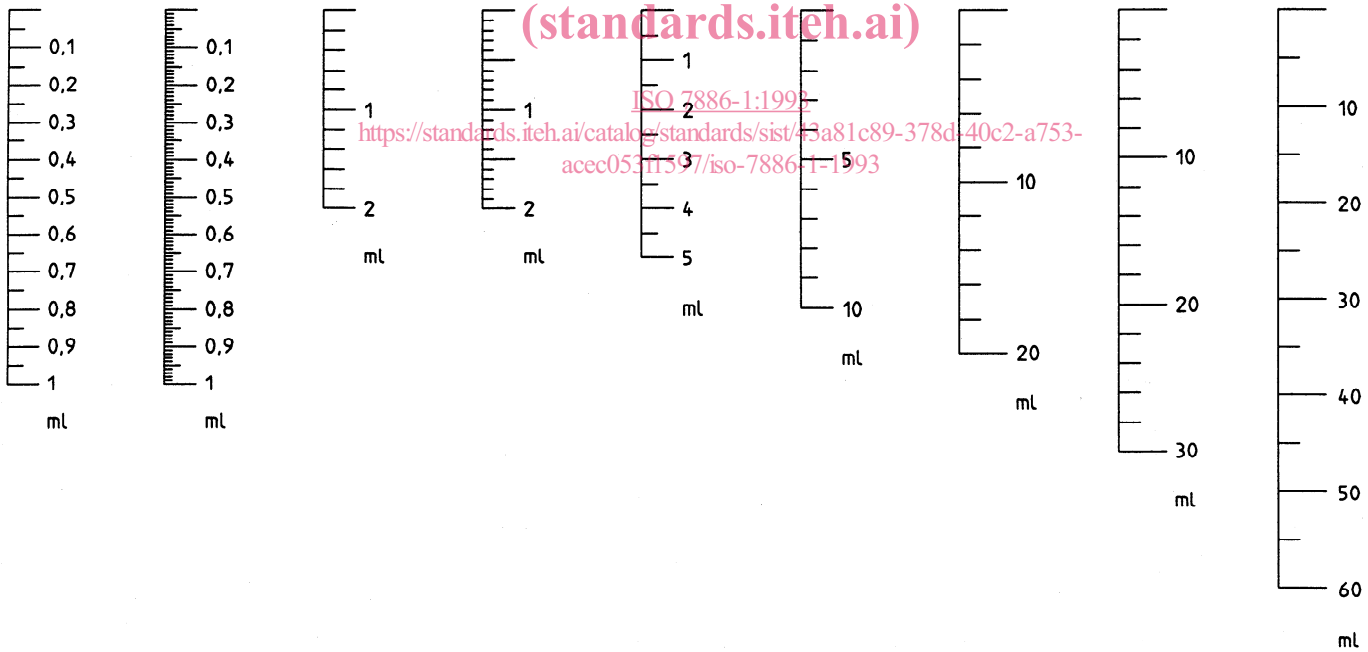
10.1.3 The graduation lines shall be of uniform thickness. They shall lie in planes at right angles to the axis of the barrel.

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

10.1.5 When the syringe is held vertically, the ends of all graduation lines of similar length shall be vertically beneath each other.

10.1.6 The lengths of the short graduation lines on each scale shall be approximately half the length of the long lines.

Examples of scales and the numbering of graduation lines are shown in figure 2.



NOTE — The vertical line of the scale may be omitted.

Not to scale.

Figure 2 — Examples of scale graduations

10.2 Numbering of scale

10.2.1 The graduation lines shall be numbered at the volume increments given in table 1. In addition, the line denoting the nominal capacity or the lines denoting the nominal capacity and the total graduated capacity, if these differ, shall be numbered.

Examples of scale numbering are shown in figure 2.

10.2.2 When the syringe is held vertically with the conical tip uppermost and with the scale to the front, the numbers shall appear vertical 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.

10.3 Overall length of scale to nominal capacity line

The overall length of the scale shall be as given in table 1.

10.4 Position of scale

When the plunger is fully inserted, that is as near to the nozzle end of the barrel as it will go, the zero graduation line of the scale shall coincide with the fiducial line on the piston to within a quarter of the smallest scale interval.

11 Barrel

11.1 Dimensions

The length of the barrel shall be such that the syringe has a maximum usable capacity of at least 10 % more than the nominal capacity.

11.2 Finger grips

The open end of the barrel shall be provided with finger grips that shall ensure that the syringe will not roll more than 180° when it is placed on a flat surface 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.

12 Piston/plunger assembly

12.1 Design

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. When tested in accordance with annex B , the piston shall not become detached from the plunger.

The plunger should be of a length adequate to allow the piston to traverse the full length of the barrel, but it should not be possible easily to withdraw the plunger completely from the barrel.

The projection of the plunger and the configuration of the push-button should be such as to allow the plunger to be operated without difficulty. When the fiducial line of the piston coincides with the zero graduation line, the preferred minimum length of the plunger from the surface of the finger grips nearer to the push-button should be:

a) 8 mm for syringes of nominal capacity up to but excluding 2 ml;

b) 9 mm for syringes of nominal capacity of 2 ml up to but excluding 5 ml;

c) 12,5 mm for syringes of nominal capacity of 5 ml and greater.

12.2 Fit of piston in barrel

When the syringe is filled with water and held vertically with first one end and then the other end uppermost, the plunger shall not move by reason of its own mass.

NOTE 5 A suggested test method and performance criteria for the forces required to move the plunger are given in annex G. It is recommended that this test be used to generate data on which to decide whether to make this test mandatory in a future revision of this part of ISO 7886.

12.3 Fiducial line

There shall be a visible and defined edge serving as the fiducial line at the end of the piston. The fiducial line shall be in contact with the inner surface of the barrel.

13 Nozzle

13.1 Conical fitting

The male conical fitting of the syringe nozzle shall be in accordance with ISO 594-1.

If the syringe has a locking fitting, it shall be in accordance with ISO 594-2.

13.2 Position of nozzle on end of barrel

13.2.1 On syringes of nominal capacity up to but not including 5 ml, the syringe nozzle shall be situated centrally, i.e. it shall be coaxial with the barrel.

13.2.2 On syringes of nominal capacity 5 ml and greater, the syringe nozzle shall be situated either centrally or eccentrically.

13.2.3 If the syringe nozzle is eccentric, its axis shall be vertically below the axis of the barrel when the syringe is lying on a flat surface with the scale uppermost. The distance between the axis of the nozzle and the nearest point on the internal surface of the bore of the barrel shall be not greater than 4,5 mm.

13.3 Nozzle lumen

The nozzle lumen shall have a diameter of not less than 1,2 mm.

14 Performance

14.1 Dead space

When tested in accordance with annex C, the volume of liquid contained in the barrel and the nozzle when the piston is fully inserted shall be as given in table 1.

14.2 Freedom from air and liquid leakage past piston

When tested in accordance with annex D, there shall be no leakage of water past the piston or seal(s).

When tested in accordance with annex B, there shall be no leakage of air past the piston or seal(s), and there shall be no fall in the manometer reading.

15 Packaging

15.1 Primary container

Each hypodermic syringe shall be sealed in a primary container.

The materials of the container should not have detrimental effects on the contents. The material and design of the container should be such as to ensure:

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

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

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

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

15.2 Secondary container

One or more primary containers shall be packaged in a secondary container.

The secondary container should be sufficiently robust to protect the contents during handling, transit and storage.

One or more secondary containers may be packaged in a storage and/or transit container.

16 Labelling

16.1 Primary container

The primary container shall be marked with at least the following information:

a) a description of the contents, including the nominal capacity and the type of nozzle;

b) the word "STERILE";

c) the words "FOR SINGLE USE" or equivalent (excepting the term "disposable"); the symbol given in annex H may also be given;

d) a warning of solvent incompatibility if necessary, for example "Not to be used with paraldehyde" (see remarks on compatibility given in the Introduction);

e) the lot number, prefixed by the word "LOT";

f) the name, trademark, trade name or logo of the manufacturer or supplier.

16.2 Secondary container

The secondary container shall be marked with at least the following information:

a) a description of the contents, including the nominal capacity, the type of nozzle and the number;

b) the word "STERILE";

c) the words "FOR SINGLE USE" or equivalent (excepting the term "disposable"); the symbol given in annex H may also be given;

d) a warning to check the integrity of each primary container before use;

e) the lot number, prefixed by the word "LOT";

f) the date (year and month expressed as specified in subclause 5.2.1.1 of ISO 8601:1988) of sterilization (the date of sterilization may be incor-