INTERNATIONAL STANDARD

ISO 7886-4

First edition
2006-10-01

Sterile hypodermic syringes for single use —

Part 4: Syringes with re-use prevention feature

Seringues hypodermiques stériles, non réutilisables —

Partie 4: Seringues avec dispositif empêchant la réutilisation

Reference number
ISO 7886-4:2006(E)

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Published in Switzerland

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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 7886-4 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*, Subcommittee SC 1, *Syringes, needles and intravascular catheters for single use*.

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 power-driven syringe pumps*

— *Part 3: Auto-disable syringes for fixed-dose immunization*

— *Part 4: Syringes with re-use prevention feature*

Introduction

The preparation of this part of ISO 7886 was recognized as a high priority requirement to prevent the re-use of syringes in the developing and transitional countries. Re-use of injection equipment in the absence of sterilization has increasingly led to transmission of blood-borne pathogens. See Reference [1] in the Bibliography.

The World Health Organisation had produced a specification for syringes that are rendered inactive after use (commonly referred to as “auto-disable” syringes) for fixed dose immunization and syringes with re-use prevention features for general purpose. Both the WHO and ISO agreed that additional parts of ISO 7886 would be required to cover syringes with re-use prevention features, whilst leaving in place ISO 7886-1 and ISO 7886-2 without modification, as a large number of devices in common use would not be intended to comply with the re-use prevention properties suggested.

This part of ISO 7886 is intended to cover syringes that are rendered inoperable after delivery of the intended dose. These syringes are not covered by ISO 7886-1 and ISO 7886-3. ISO 7886-2 covers syringes used with power-driven pumps. Given the diversity of clinical applications, the most appropriate re-use prevention feature offering the highest level of re-use prevention is to be considered for each specific intended use.

It is recognized that syringes designed to reduce the risk of needlestick injuries can also comply with this part of ISO 7886 with regard to their re-use prevention properties, but it is stressed that anti-needlestick properties of syringes are not in themselves addressed in this part of ISO 7886.

Sterile hypodermic syringes for single use —

Part 4:
Syringes with re-use prevention feature

1 Scope

This part of ISO 7886 specifies requirements for sterile single-use hypodermic syringes made of plastics materials with or without needle, and intended for the aspiration of fluids or for the injection of fluids immediately after filling and of design such that the syringe can be rendered unusable after use.

This part of ISO 7886 is not applicable to syringes made of glass (specified in ISO 595), auto-disable syringes for fixed dose immunization (ISO 7886-3) and syringes designed to be pre-filled. It does not address compatibility with injection fluids. Other standards can be applicable when syringes are used for any other intended purpose than those specified in this part of ISO 7886.

NOTE Syringes designed to reduce the risk of needlestick injuries can also comply with this part of ISO 7886 with regard to their re-use prevention properties, but it is stressed that anti-needlestick properties of syringes are not in themselves addressed in this part of ISO 7886.

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 780, *Packaging — Pictorial marking for handling of goods*

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

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

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

ISO 7886-1:1993, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*

ISO 8537:1991, *Sterile single-use syringes, with or without needle, for insulin*

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

ASTM D999-01, *Standard methods for vibration testing of shipping containers*

ASTM D5276-98, *Standard test method for drop test of loaded containers by free fall*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7886-1, ISO 8537 and the following apply.

3.1
re-use prevention feature
feature that either automatically activates upon or during administration of the intended dose or is activated by the user to prevent subsequent re-use of the syringe

4 Nomenclature

The nomenclature for components of syringes with re-use prevention feature is shown in Figure 1.

5 Types of syringe

5.1 General

Syringe types shall be categorized in accordance with 5.2 and 5.3.

Given the diversity of clinical applications, the most appropriate re-use prevention feature offering the highest level of re-use prevention should be considered for each specific intended use.

5.2 Re-use prevention feature

The re-use prevention feature shall be categorized as follows;

— **Type 1**: operates automatically during or upon completion of intended single use;

— **Type 2**: requires elective activation upon completion of intended single use.

5.3 Intended use/application

The intended use/application shall be categorized as follows;

— **Type A**: single aspiration and injection;

— **Type B**: multiple plunger aspirations prior to the final intended single use.

6 Cleanliness

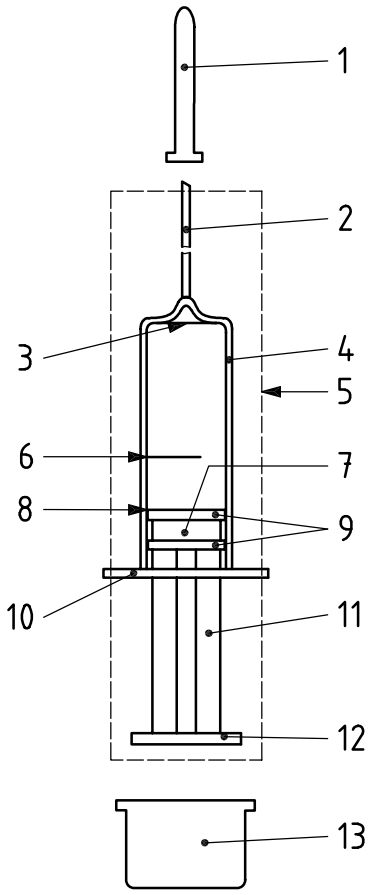
The requirements of Clause 5 of ISO 7886-1:1993 apply.

7 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.

8 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.



Key

1 needle cap/protective end cap (if used)
2 needle
3 zero line
4 barrel
5 re-use prevention feature
6 nominal capacity line
7 piston
8 fiducial line
9 seal(s)
10 finger grips
11 plunger
12 push-button
13 protective end cap (if used)

NOTE 1 The syringe can have graduated scale lines in accordance with ISO 7886-1.

NOTE 2 This illustration can be considered as reference for nomenclature of components. The configuration and design can vary with the design of syringe.

NOTE 3 The drawing is intended to be illustrative of components of a syringe with a re-use prevention feature.

Figure 1 — Schematic representation of a syringe with re-use prevention feature

9 Lubricant

The requirements of Clause 8 of ISO 7886-1:1993 and 11.4 of ISO 7864:1993 apply.

10 Tolerance on graduated capacity

The tolerances on the graduated capacity shall be as given in ISO 7886-1:1993, Table 1 or, for insulin syringes, shall be as given in reference ISO 8537:1991, Table 1.

11 Graduated scale

11.1 Scale

Graduated scales shall comply with 10.1 of ISO 7886-1:1993 or 9.1 of ISO 8537:1991.

11.2 Numbering of scale

The requirements of 10.2 of ISO 7886-1:1993 or 9.2 of ISO 8537:1991 apply as appropriate.

11.3 Position of scale

The requirements of 10.4 of ISO 7886-1:1993 apply.

11.4 Overall length of scale to nominal capacity line

The requirements of 10.3 of ISO 7886-1:1993 or 9.3 of ISO 8537:1991 apply except for fixed dose scales.

12 Barrel

12.1 Dimensions

The length of the barrel and the design of the re-use prevention feature shall be such that the syringe has a recommended maximum usable capacity of at least 5 % more than the nominal capacity and a recommended maximum capacity of 20 % more that the nominal capacity.

12.2 Finger grips

The requirements of 11.2 of ISO 7886-1:1993 apply.

13 Piston/plunger assembly

13.1 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 a syringe with integrated needle is tested in accordance with Annex B of ISO 8537:1991 or a syringe without needle is tested in accordance with Annex B of ISO 7886-1:1993, the piston shall not inadvertently become detached from the plunger during intended use. 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 plunger is positioned to begin the filling process, the preferred minimum length of the plunger from the surface of the finger grips 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.

13.2 Fit of the piston in the barrel

For general use syringes, the requirements of 12.2 of ISO 7886-1:1993 apply. For insulin syringes, 11.3 of ISO 8537:1991 applies.

13.3 Fiducial line

The requirements of 12.3 of ISO 7886-1:1993 or 11.3 of ISO 8537:1991 apply as appropriate.

14 Syringe nozzle/needle

14.1 Syringe with integrated needle

Syringes with integrated needle shall have a minimum needle union force applied as pull in the direction of the needle axis in accordance with ISO 7864:1993.

Needle tubing shall be in accordance with ISO 9626.

14.2 Syringe with Luer nozzle

Syringes with male conical fittings shall be in accordance with Clause 13 of ISO 7886-1:1993.

15 Performance

15.1 Dead space

When tested in accordance with Annex E of ISO 8537:1991, the dead space shall not exceed the limits specified in 14.1 of ISO 7886-1:1993. This dead space requirement refers to syringes without needles attached; for syringes supplied with attached needles, the dead space volume of the needle shall be subtracted.

15.2 Freedom from air and liquid leakage

When syringes with integrated needles are tested in accordance with Annex F of ISO 8537:1991 and syringes without needles are tested in accordance with Annex D of ISO 7886-1:1993, there shall be no leakage of water past the piston or seal(s).

When syringes with integrated needles are tested in accordance with Annex B of ISO 8537:1991 and syringes without needles are tested in accordance with Annex B of ISO 7886-1:1993, there shall be no leakage of air past the piston or seal(s), and there shall be no fall in the manometer reading.

For syringes with integrated needles, the requirements of 14.2 of ISO 8537:1991 apply.

Leakage resistance should be demonstrated irrespective of the re-use prevention feature.

15.3 Re-use prevention feature

Once the re-use prevention feature has been activated in accordance with the manufacturer’s instruction, it shall not be possible to re-use the syringe under the normal conditions of use, or by testing in accordance with the test method in Annex B.

15.4 Performance after shipping

There shall be no effect on the performance of the syringe when tested in accordance with ASTM D999-01 and ASTM D5276-98.

15.5 Guidance on materials

Guidance on some aspects of the selection of materials is given in Annex E of ISO 7886-1:1993.

16 Packaging

16.1 Primary container

The requirements of 15.1 of ISO 8537:1991 apply.

16.2 Secondary container

The requirements of 15.2 of ISO 7886-1:1993 apply.

17 Labelling

17.1 General

Labelling shall be legible and discernible under normal or corrected to normal vision.

17.2 Primary container

17.2.1 Self-contained syringe unit

The self-contained syringe unit shall bear at least the following information:

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

b) the symbol for “re-use prevention” given in Figure 2;

c) the name and/or trade mark of the manufacturer;

d) the words “sterile interior” or equivalent symbol;

e) the lot number prefixed by the word “LOT” (or equivalent harmonized symbol);

f) the expiry date (year and month), prefixed by the word “EXP” (or an equivalent harmonized symbol);

g) the external diameter and length of the needle, if included.

17.2.2 Unit container

The unit container shall bear at least the following information:

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

b) the symbol for “re-use prevention”, given in Figure 2;

c) the name and/or trade mark of the manufacturer;

d) the words “sterile” or equivalent harmonized symbol;

e) the lot number prefixed by the word “LOT” (or equivalent harmonized symbol);

f) the expiry date (year and month), prefixed by the word “EXP” (or an equivalent harmonized symbol);

g) a description of the contents, including the nominal capacity of the syringe and the external diameter and length of the needle, if included.

17.3 Secondary container

The secondary container shall bear at least the following information:

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

b) the symbol for “re-use prevention” given in Figure 2;

c) the name and/or trade mark and address of the manufacturer;

d) the words “sterile” or equivalent harmonized symbol;

e) the lot number prefixed by the word “LOT” (or equivalent harmonized symbol);

f) the expiry date (year and month), prefixed by the word “EXP” (or an equivalent harmonized symbol);

g) a description of the contents, including the nominal capacity of the syringe and the external diameter and length of the needle, if included;

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

i) a warning not to recap the needle, or equivalent symbol;

j) information for handling, storage and disposal of syringe; for illustration see Figure 3;

k) instructions for use, including instructions appropriate to the re-use prevention feature shall be given either on the package or on a separate insert;

l) the number of units per secondary container.

17.4 Storage container

The storage container shall bear at least the following information:

a) a description of the contents, including the nominal capacity of the syringe and the external diameter and length of the needle, if included;

b) the symbol for "re-use prevention" given in Figure 2.

c) the lot number prefixed by the word "LOT" (or equivalent harmonized symbol);

d) the expiry date (year and month), prefixed by the word "EXP" (or an equivalent harmonized symbol);

e) the words "sterile" or equivalent harmonized symbol;

f) the name and/or trade mark and address of the manufacturer;

g) information for handling, storage and transportation of the contents (or equivalent symbols as specified in ISO 7000 or ISO 780);

h) the number of units per storage container.

17.5 Transport wrapping

If a storage container is not used but the secondary containers are wrapped for transportation, the information required by 17.4 shall either be marked on the wrapping or shall be visible through the wrapping.

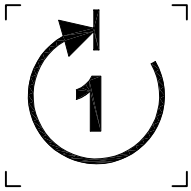


Figure 2 — Symbol ISO 7000-2655 for "re-use prevention"

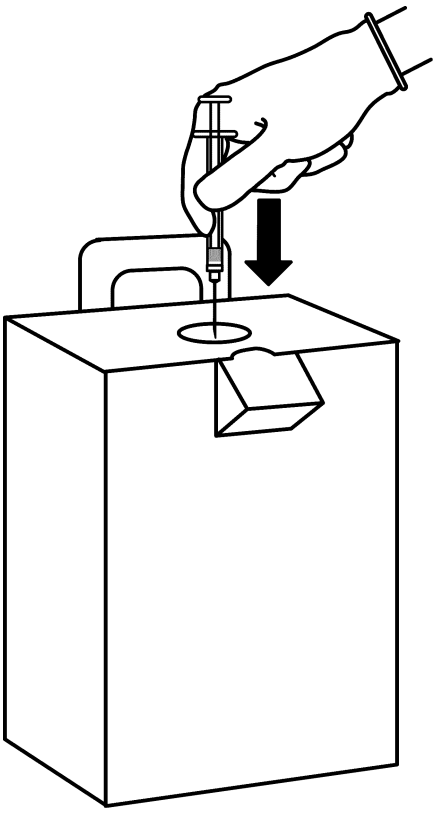


Figure 3 — Example of a diagram to illustrate safe disposal of syringe

Annex A
(normative)

Method for preparation of extracts

A.1 Principle

The syringe, including the needle (if supplied), is filled with water in order to extract soluble components.

A.2 Apparatus and reagents

A.2.1 **Freshly distilled or deionized water**, of Grade 3 in accordance with ISO 3696:1987.

A.2.2 **Selection of laboratory borosilicate glassware**.

A.3 Procedure

A.3.1 Fill at least three syringes to the nominal capacity graduation line with water (A.2.1), expel air bubbles and maintain the syringes, including the needle, at a temperature of 37 °C $^{+3}_{0}$ °C for 8 h $^{+15}_{0}$ min.

Eject the contents and combine them in a vessel made of borosilicate glass (A.2.2).

A.3.2 Prepare the control fluid by reserving a portion of the unused water (A.2.1).

Annex B
(normative)

Test method for testing re-use prevention feature for RUP syringes

B.1 Principle

To show that inactivated re-use prevention feature (RUP) syringe is incapable of being re-used, a mechanical testing machine or pressure device is used to move the plunger out of the barrel and the force is recorded. This method is used, where applicable to the design of syringe (see 15.3).

B.2 Apparatus

B.2.1 Device for applying an axial force up to a maximum of 100 N, while moving the plunger with a speed of 100 mm/min.

B.2.2 Device for applying a back-pressure of approximately 100 kPa/min, up to 300 kPa gauge.

B.3 Procedure

B.3.1 Withdrawal test

Fill the syringe with water, expel all air bubbles and line up the plunger to the nominal volume scale mark, and then expel the fluid. Activate the RUP as required. Attempt to refill the syringe by applying an increasing force up to a maximum of 100 N to the plunger or until the syringe is refilled.

If the syringe can be re-used after a withdrawal force of less than 100 N, the syringe has failed the test.

B.3.2 Back pressure

Fill a second syringe with water, expel all air bubbles and line up the plunger to the nominal volume scale mark and then expel the fluid. Activate the RUP as required. Subject the syringe to a slowly increasing back-pressure at a rate of approximately 100 kPa/min up to 300 kPa applied through the needle or Luer nozzle and record whether the piston seal can be driven back in the syringe barrel.

If the syringe can be re-used after a back-pressure of less than 300 kPa, the syringe has failed the test.

B.4 Test report

The test report shall contain at least the following information:

a) a reference to this part of ISO 7886 (ISO 7886-4:2006)

b) the identity and nominal capacity of the syringe;

c) the maximum force applied;

d) the maximum pressure applied;

e) the date of testing;

f) conclusion and outcome of the test.

Annex C
(informative)

Environmental aspects

Planning and design of products applying to this International Standard should consider the environmental impact from the product during its life cycle. The environmental impact generated by a syringe with re-use prevention feature is mainly restricted to the following occurrences:

— impact at local environment during normal use;

— safe disposal at the end of the life cycle.

To highlight the importance of reducing the environmental burden, this part of ISO 7886 addresses requirements or recommendations intended to decrease environmental impact caused by those aspects.

See Table C.1 for a mapping of the life cycle of a syringe with re-use prevention feature to aspects of the environment.

Table C.1 — Environmental aspects addressed by clauses of this part of ISO 7886

Environmental aspects (inputs and outputs)		Product life cycle			
		Production and preproduction Stage A	Distribution (including packaging) Stage B	Use Stage C	End of life Stage D
		Addressed in subclause	Addressed in subclause	Addressed in subclause	Addressed in subclause
1	Resource use	—	—	—	—
2	Energy consumption	—	—	—	—
3	Emissions to air	—	—	—	17.3 j)
4	Emissions to water	—	—	7, 8	17.3 j)
5	Waste	—	16, 17.5	—	—
6	Noise	—	—	—	—
7	Migration of hazardous substances	—	—	7, 8	17.3 j)
8	Impacts on soil	—	—	—	17.3 j)
9	Risks to the environment from accidents or misuse	—	—	5, 15.3 17.2.1 a) b) 17.2.2 a) b) 17.3 a) b) h) j) 17.4 b)	17.3 j)

Bibliography

[1] WHO/V&B/99.25, *WHO-UNICEF-UNFPA joint statement on the use of auto-disable syringes in immunization services*

[2] ISO 7886-2, *Sterile hypodermic syringes for single use — Part 2: Syringes for use with power-driven syringe pumps*

[3] ISO 7886-3, *Sterile hypodermic syringes for single use — Part 3: Auto-disable syringes for fixed-dose immunization*

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