INTERNATIONAL STANDARD

ISO 7886-4

Second edition
2018-11

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 7886-4:2018(E)

COPYRIGHT PROTECTED DOCUMENT

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: 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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*.

This second edition cancels and replaces the first edition (ISO 7886-4:2006), which has been technically revised. The main changes compared to the previous edition are as follows:

— terminology in Introduction is clarified;

— general reference update (Normative references, Bibliography and main body of the text);

— definitions for "active activation" and "auto-disable feature" added;

— test of syringes: Harmonized definitions with ISO 7886-3 and clarified text;

— Figure 1 is removed and substituted with a reference to the figure in ISO 7886-1;

— barrel dimension – the additional 20 % capacity is removed;

— dimensions in design section are clarified;

— alignment with ISO 7886-1 and ISO 7886-3;

— subclause 15.5, Guidance on material, has been removed;

— Figure 3 (safety box) is removed;

— Annex C is deleted.

A list of all parts in the ISO 7886 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The preparation of this document was recognized as a high priority requirement to prevent intentional (misuse) or accidental reuse of syringes. Re-use of injection equipment in the absence of sterilization has increasingly led to transmission of blood-borne pathogens. See Reference [5] in the Bibliography.

The World Health Organisation (WHO) had produced a specification for syringes that are rendered inactive after use [commonly referred to as "auto-disable" (AD) syringes] for both fixed dose immunization and syringes with re-use prevention features for general/curative purposes and the reconstitution of vaccines. For the purpose of this document, auto disabled is used for the feature of type 1 re-use prevention which operates automatically during or upon completion of the intended single use. Both the WHO and ISO agreed that additional parts of ISO 7886 would be required to cover syringes with re-use prevention features, while 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 document is intended to cover syringes that are rendered inoperable, either during or upon completion or 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 needle-stick injuries can also comply with this document with regard to their re-use prevention properties, but it is stressed that anti-needle-stick properties of syringes are not in themselves addressed in this document.

Guidance on transition periods for implementing the requirements of this document is given in ISO/TR 19244.

Sterile hypodermic syringes for single use —

Part 4:
Syringes with re-use prevention feature

1 Scope

This document specifies requirements for sterile single-use hypodermic syringes made of plastic and rubber 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 document is not applicable to syringes made of glass [specified in ISO 595 (withdrawn)], 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 document.

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 7864:2016, *Sterile hypodermic needles for single use — Requirements and test methods*

ISO 7886-1:2017, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*

ISO 8537:2016, *Sterile single-use syringes, with or without needle, for insulin*

ISO 9626, *Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods*

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.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

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

3.2
active activation
activation of the *reuse prevention feature* (3.1) that does require an additional step by the user

3.3
auto disable feature
feature that automatically activates, prior to end of injection, to render the syringe unusable by the delivery of the intended dosage

4 Types of syringe

4.1 General

Syringe types shall be categorized in accordance with 4.2 and 4.3.

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.

4.2 Types of re-use prevention feature

The re-use prevention feature shall be either:

— Type 1: auto-disabled feature;

— Type 2: feature that requires elective activation upon completion of intended single use (i.e. active activation).

4.3 Types of intended use/application

The intended use/application shall be one of the following:

— Type A: design that allows for only a single aspiration and injection;

— Type B: design that allows for multiple plunger aspirations prior to the final intended single use.

5 Extraneous matter

5.1 General

The requirements of ISO 7886-1:2017, 6.1 apply.

5.2 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.

5.3 Limits for extractable metals

When tested by a recognized micro-analytical method, for example by an atomic absorption method or by an inductively coupled plasma mass spectrometry method (ICP), 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.

6 Lubricant

The requirements of ISO 7886-1:2017, Clause 7 and ISO 7864:2016, 11.4 apply.

7 Tolerance on graduated capacity

The tolerances on the graduated capacity shall be as given in ISO 7886-1:2017, Table 1 or, for insulin syringes, shall be as given in ISO 8537:2016, Table H.1.

8 Graduated scale

8.1 Scale

Graduated scales shall comply with ISO 7886-1:2017, 9.1 or ISO 8537:2016, 5.1.

8.2 Numbering of scale

The requirements of ISO 7886-1:2017, 9.2 or ISO 8537:2016, 5.1 apply as appropriate.

8.3 Position of scale

The requirements of ISO 7886-1:2017, 9.4 apply.

8.4 Overall length of scale to nominal capacity line

The requirements of ISO 7886-1:2017, 9.3 or ISO 8537:2016, Table H.1 apply, except for fixed dose scales.

9 Barrel

9.1 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 capacity that is determined by risk assessment with consideration of, for example, removal of air bubbles or risk of overdose.

9.2 Barrel flanges

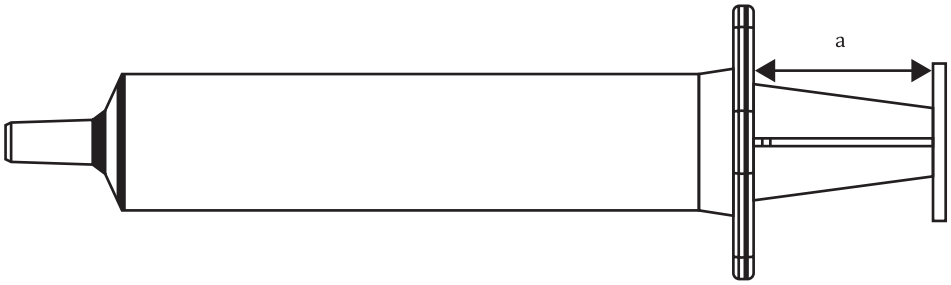
The requirements of ISO 7886-1:2017, 10.2 apply.

10 Plunger stopper/plunger assembly

10.1 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 ISO 8537:2016, Annex B or a syringe without needle is tested in accordance with ISO 7886-1:2017, Annex B, the plunger stopper 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 fiducial line of the plunger stopper coincides with the zero graduation line, the minimum length of the

plunger from the surface of the barrel flanges nearer to the push-button, as shown in Figure 1, shall be at least 8 mm.



Key

a Minimum 8 mm.

Figure 1 — Minimum length between barrel flanges and plunger push-button

10.2 Fit of plunger stopper/plunger in the barrel

For general use syringes, the requirements of ISO 7886-1:2017, 13.4 apply. For insulin syringes, ISO 8537:2016, 5.7.2 applies.

10.3 Fiducial line

The requirements of ISO 7886-1:2017, 9.4 apply.

11 Syringe nozzle/needle

11.1 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.

Needle tubing shall be in accordance with ISO 9626.

11.2 Syringe with Luer nozzle

Syringes with male conical fittings shall be in accordance with ISO 7886-1:2017, Clause 12.

12 Performance

12.1 Dead space

When tested in accordance with ISO 8537:2016, Annex D, the dead space shall not exceed the limits specified ISO 7886-1:2017, 13.1. 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.

12.2 Freedom from air and liquid leakage

When syringes with integrated needles are tested in accordance with ISO 8537:2016, Annex E and syringes without needles are tested in accordance with ISO 7886-1:2017, Annex D, there shall be no leakage of water past the plunger stopper or seal(s). Small droplets between the seals are not considered failure.

When syringes with integrated needles are tested in accordance with ISO 8537:2016, Annex F and syringes without needles are tested in accordance with ISO 7886-1:2017, Annex B, there shall be no leakage of air past the plunger stopper or seal(s), and there shall be no fall in the manometer reading.

For syringes with integrated needles, the requirements of ISO 8537:2016, 5.11.2 and 5.11.3 apply.

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

12.3 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.

12.4 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.

13 Packaging

13.1 Unit packaging and self-contained syringe units

The requirements of ISO 8537:2016, 6.1 apply.

13.2 Multiple unit pack

The requirements of ISO 7886-1:2017, 14.2 apply.

13.3 User packaging

The requirements of ISO 7886-1:2017, 14.3 apply.

14 Information supplied by the manufacturer

14.1 General

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

14.2 Syringes

14.2.1 General

The requirements of ISO 7886-1:2017, 15.2.1 apply.

14.2.2 Unit packaging

The unit container shall bear at least the following information:

a) the requirements of ISO 7886-1:2017, 15.3 apply;

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

14.3 Multiple unit packs

14.3.1 General

Multiple unit packs shall bear the following information:

a) the requirements of ISO 7886-1:2017, 15.4.1 apply;

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

14.3.2 Multiple unit packs with self-contained syringes

Multiple unit packs with self-contained syringes shall bear the following information:

a) the requirements of ISO 7886-1:2017, 15.4.2 apply;

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

c) information for handling, storage and disposal of syringe;

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

14.4 User packaging

14.4.1 General

User packaging shall bear the following information:

a) the requirements of ISO 7886-1:2017, 15.5 apply;

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

14.4.2 Storage container

The storage container shall bear at least the following information:

a) the requirements of ISO 7886-1:2017, 15.6 apply;

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

c) the number of units per storage container.

14.5 Transport wrapping

If a storage container is not used but the secondary containers are wrapped for transportation, the information required by 14.4.2 shall either be marked on the wrapping or shall be visible through the wrapping.

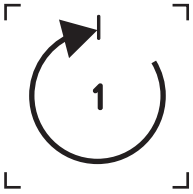


Figure 2 — Symbol ISO 7000-2655 for “re-use prevention”

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.

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

B.1 Principle

To show that the activated re-use prevention feature 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 14.3).

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 re-use prevention feature 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 re-use prevention feature 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 plunger stopper 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 document, i.e. ISO 7886-4:2018;

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.

Bibliography

[1] ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

[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-disabled syringes for fixed-dose immunization*

[4] ISO/TR 19244, *Guidance on transition periods for standards developed by ISO/TC 84 — Devices for administration of medicinal products and catheters*

[5] WHO/HIS/SDS/ 2015.5, *WHO guideline on the use of safety-engineered syringes for intramuscular, intradermal and subcutaneous injections in health-care settings*

ICS 11.040.25
Price based on 10 pages