INTERNATIONAL STANDARD

ISO 7886-3

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Sterile hypodermic syringes for single use —

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

Seringues hypodermiques stériles, non réutilisables —

Partie 3: Seringues autobloquantes pour vaccination à dose fixe

Reference number
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Foreword

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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 7886-3 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 reuse prevention feature*

For the purposes of this part of ISO 7886, the CEN annex regarding fulfilment of European Council Directives has been removed.

Introduction

ISO 7886 was first published in 1984. It was subsequently decided to divide it into two parts, ISO 7886-1 retaining essentially the scope of ISO 7886:1984, and ISO 7886-2 being applicable to sterile, single-use syringes for use with power-driven pumps.

The preparation of this third part of ISO 7886 was recognized as a high priority requirement to prevent the re-use of fixed dose immunization 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.

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

This part of ISO 7886 is intended to cover “fixed dose” immunization syringes that are rendered inoperable after delivery of the intended dose. These syringes are not covered by Parts 1 and 2 of ISO 7886.

It is recognized that syringes designed to reduce the risk of needlestick injuries, in addition to preventing sharps injuries, may also comply with this part of ISO 7886 with regard to their auto-disable 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 3:
Auto-disable syringes for fixed-dose immunization

1 Scope

This part of ISO 7886 specifies the properties and performance of sterile single-use hypodermic syringes with or without needle, made of plastic materials and stainless steel and intended for the aspiration of vaccines or for the injection of vaccines immediately after filling. Upon delivering a fixed dose of vaccine, the syringe is automatically rendered unusable.

This part of ISO 7886 does not specify the design of the auto-disable feature, which is left to the discretion of the manufacturer.

This part of ISO 7886 is not applicable to syringes for use with insulin (specified in ISO 8537), syringes made of glass (specified in ISO 595), syringes for use with power-driven syringe pumps (specified in ISO 7886-2), auto-disable syringes for variable dose delivery and syringes designed to be prefilled. It does not address compatibility with injection fluids/vaccines.

NOTE A fourth part of ISO 7886 is being prepared to cover syringes with reuse prevention feature.

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

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*

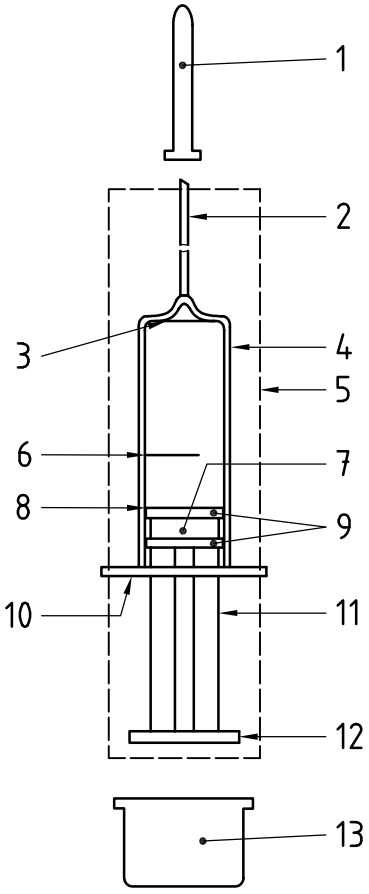
3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7886-1:1993 (except 3.2) and ISO 8537:1991 (except 3.1) and the following apply.

3.1
auto-disable syringe feature
feature that automatically activates upon administration of the intended fixed dose to prevent subsequent re-use of the syringe and the needle

4 Nomenclature

The nomenclature for components of auto-disable syringes for fixed dose is shown in Figure 1.



Key

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

NOTE The drawing is intended to be illustrative of components of an auto-disable syringe only.

Figure 1 — Schematic representation of auto-disable syringe for fixed dose

5 Cleanliness

Clause 5 of ISO 7886-1:1993 shall apply.

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 no 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

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

9 Tolerance on nominal capacity

The volume of water at (20 ± 5) °C [or, for tropical countries (27 ± 5) °C] expelled from the syringe when the fiducial line of the piston traverses the full scale (i.e. the intended fixed dose) shall be within the tolerances on the nominal capacity as specified in Table 1.

Table 1 — Nominal capacity and dead space

Nominal capacity ml	Tolerance on nominal capacity %	Maximum dead space for integrated and non-integrated needle ml
$0{,}05 \leqslant V \leqslant 0{,}2$	± 20 %	0,025
$0{,}2 < V \leqslant 2$	± 5 %	0,07

10 Graduated scale

10.1 Scale

The scale shall have only two markings, the zero line and the nominal capacity line (i.e. the total graduated capacity line). These lines shall be of uniform thickness. They shall lie in planes at right angles to the axis of the barrel.

10.2 Position of scale

10.4 of ISO 7886-1:1993 shall apply.

11 Barrel

11.1 Dimensions

The length of the barrel and the design of the auto-disable feature shall be such that the syringe has a maximum usable capacity of at least 10 % more than the nominal capacity and a recommended maximum capacity of 20 % more than the nominal capacity.

11.2 Finger grips

11.2 of ISO 7886-1:1993 shall apply.

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. The piston shall not become detached from the plunger when tested in accordance with Annex B of ISO 8537:1991 for a syringe with integrated needle or in accordance with Annex B of ISO 7886-1:1993 for a syringe without needle.

The plunger should be of a length adequate to allow the piston properly to deliver the designated fixed dose. It should not be possible to defeat the auto-disable feature by removing and re-inserting the plunger.

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 shall be 8 mm.

12.2 Fit of the piston in the barrel

12.2 of ISO 7886-1:1993 shall apply.

NOTE Annex B gives a suggested test method and performance criteria for the forces required to move the plunger.

12.3 Fiducial line

12.3 of ISO 7886-1:1993 shall apply.

13 Needle

13.1 Integrated needle

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

Needle tubing shall be in accordance with ISO 9626.

13.2 Non-integrated needle

If a non-integrated needle is used, it shall become an integral part of the syringe and cannot be detached. Both the needle and the syringe shall be rendered incapable of re-use after delivery of the intended fixed dose, under normal conditions of use.

14 Performance

14.1 Dead space

When a syringe with needle is tested in accordance with Annex E of ISO 8537:1991, the dead space shall not exceed the limits given in Table 1.

14.2 Freedom from air and liquid leakage

When a syringe with integrated needle is tested in accordance with Annex F of ISO 8537:1991 and a syringe without needle is 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 a syringe with integrated needle is tested in accordance with Annex B of ISO 8537:1991 and a syringe without needle is 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 needle, 14.2 of ISO 8537:1991 shall apply.

14.3 Auto-disable feature

The syringe and needle shall be passively and automatically rendered unusable by the delivery of the intended fixed dose. No secondary or additional action on the part of the user shall be required.

The timing of the activation of the auto-disable feature may vary by design, typically within the ranges described below:

— the auto-disable feature is automatically activated and remains effective from the time that the injection is commenced;

— the auto-disable feature is automatically activated and remains effective from the point when 50 % of the intended fixed dose has been delivered;

— the auto-disable feature is automatically activated on completion of the delivery of the intended fixed dose.

In all cases, once the auto-disable feature has been activated:

a) it shall not be possible to re-use the syringe and the needle under the normal conditions of use,

b) it shall not be possible to override the auto-disable feature when tested in accordance with the test method in Annex C, i.e. it shall not be possible to re-use the syringe after applying a force of 100 N at a speed of 100 mm/min on the plunger or a back pressure on the needle of 100 kPa/min up to 300 kPa.

14.4 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.

14.5 Guidance on materials

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

15 Packaging

15.1 Primary and unit containers and self-contained syringe units

15.1 of ISO 8537:1991 shall apply.

15.2 Secondary containers

15.2 of ISO 7886-1:1993 shall apply.

16 Labelling

16.1 Primary and unit containers and self-contained syringe units

16.1.1 Self-contained syringe units

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 indicating that the device possesses an auto-disable function for re-use prevention as given in Figure 2;

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

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

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

16.1.2 Primary and unit containers

The primary and/or 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 indicating that the device possesses an auto-disable function for re-use prevention as given in Figure 2;

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

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

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

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

g) the description of contents including the nominal capacity and type of the needle, if included.

16.2 Secondary containers

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 indicating that the device possesses an auto-disable function for re-use prevention as given in Figure 2;

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

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

g) the description of the contents including the nominal capacity and type 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) any information for handling, storage and disposal of syringe;

NOTE An example of an illustration of safe disposal of a syringe is given in Figure 3.

k) the instructions for use, including the instructions appropriate to the auto-disable feature; alternatively, the instructions for use can be indicated on a separate insert;

l) the number of units per secondary container.

16.3 Storage containers

The storage container shall bear at least the following information:

a) the description of contents including the nominal capacity and the type of needle, if included;

b) the symbol indicating that the device possesses an auto-disable function for re-use prevention is given in Figure 2;

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

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

e) the word “sterile” or equivalent harmonized symbol;

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

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

h) the number of units per storage container.

16.4 Transport wrapping

If a storage container is not used but the secondary containers are wrapped for transportation, the information required by 16.3 shall either be marked on the wrapping or shall be visible through the wrapping.

Figure 2 — Graphical symbol for the auto-disable function (ISO 7000-2655)

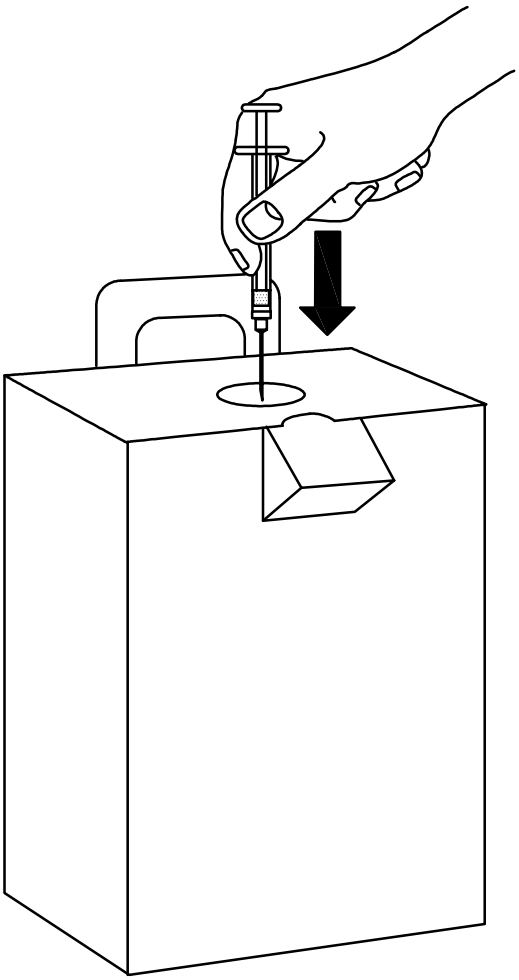


Figure 3 — Example of a diagram to illustrate safe disposal of syringe

Annex A
(normative)

Method for preparation of extracts

A.1 Principle

The syringe, including the needle (if available), 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 **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 $(37^{+3}_{0})\,°C$ 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
(informative)

Test method for forces required to operate plunger

B.1 Principle

A mechanical testing machine (see Figure G.1 in ISO 7886-1:1993) is used to move the syringe plunger and to aspirate and expel water, whilst the force exerted and the plunger travel are recorded.

B.2 Apparatus and reagents

B.2.1 Mechanical testing machine, capable of measuring and continuously recording force and travel with an accuracy of 1 % of full scale reading and having means for attaching the syringe to be tested.

B.2.2 Reservoir for testing non-integrated needle type, open to the atmosphere, and having tubing of inside diameter (2,7 ± 0,1) mm for connecting it to the syringe to be tested.

B.2.3 Reservoir for testing integrated needle type, open to the atmosphere, and having tubing of inside diameter (2,7 ± 0,1) mm closed with a rubber stopper for connecting it to the needle of the syringe to be tested.

B.2.4 Water.

B.3 Procedure

B.3.1 Remove the syringe from the package and mount it in the testing machine (B.2.1).

B.3.2 Connect the syringe using one of the following procedures.

— Testing non-integrated needle type.

Connect the nozzle of the syringe to the tubing of the reservoir (B.2.2). Add water (B.2.4) at (23 ± 2) °C to the reservoir and displace any air from the tubing. Maintain the water and the syringe at this temperature. Adjust the relative positions of the syringe and reservoir so that the water level in the reservoir is approximately level with the mid-point of the syringe barrel.

— Testing integrated needle type.

Connect the needle of the syringe to the rubber stopper of the tubing of the reservoir (B.2.3). Add water (B.2.4) at (23 ± 2) °C to the reservoir and displace any air from the tubing. Maintain the water and the syringe at this temperature. Adjust the relative positions of the syringe and reservoir so that the water level in the reservoir is approximately level with the mid-point of the syringe barrel.

B.3.3 Zero the recorder and set the testing machine (B.2.1) so that it can apply compressive and tensile forces without re-setting.

B.3.4 Start the testing machine so that it withdraws the syringe plunger, at a rate of (100 ± 5) mm/min, to the graduation line that indicates the nominal capacity, thereby drawing water from the reservoir to the syringe. Stop the plunger travel and readjust the recorder to zero. Wait 30 s.

NOTE The presence of air in the syringe nozzle or needle, irrespective of whether the syringe is of the non-integrated or integrated needle type, will not affect the results of the test.

B.3.5 Reverse the testing machine and return the plunger so that the fiducial line reaches the zero graduation line, thereby expelling the water from the syringe into the reservoir.

B.4 Calculation of results

B.4.1 From the recording of plunger travel and force applied (see Figure G.2 in ISO 7886-1:1993), determine the following:

a) the force required (F_s) to initiate movement of the plunger, i.e. the peak force recorded when the testing machine starts to withdraw the plunger (see B.3.4);

b) the mean force (F) during return of the plunger [i.e. the estimated or integrated mean value while the testing machine is returning the plunger (see B.3.5)];

c) the maximum force (F_{max}) during return of the plunger (see B.3.5);

d) the minimum force (F_{min}) during return of the plunger (see B.3.5).

B.4.2 Proposed values for the forces required to operate the plunger are given in Table B.1.

Table B.1 — Proposed values for forces required to operate plunger

Nominal capacity of syringe	Maximum initial force	Mean force	Maximum force	Minimum force
V	F_s	F	F_{max}	F_{min}
ml	N	N	N	N
$V < 2$	10	9	2 × measured F or measured F + 1,5 N whichever is the higher	0,5 × measured F or measured F − 1,5 N whichever is the lower

B.5 Test report

The test report shall contain at least the following information:

a) the identity and nominal capacity of syringe;

b) the force (F_s) required to initiate movement of the plunger, expressed in newtons;

c) the mean force (F) during return of the plunger, expressed in newtons;

d) the maximum force (F_{max}) during return of the plunger, expressed in newtons;

e) the minimum force (F_{min}) during return of the plunger, expressed in newtons;

f) the date of testing.

Annex C
(normative)

Test method for testing auto-disable feature

C.1 Principle

After delivery of a full dose of vaccine or distilled water under normal conditions of use, a mechanical testing machine or pressure device is used to move the plunger out of the barrel and the force required to move the plunger and/or to destroy the barrel is measured and recorded.

C.2 Apparatus

C.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.

C.2.2 Device to apply a back-pressure, at a rate of approximately 100 kPa/min for an applied pressure of up to 300 kPa.

C.3 Procedure

C.3.1 Deliver a full dose of vaccine or distilled water under normal conditions of use. Using the test device (C.2.1) impose an increasing force on the plunger to withdraw it from the barrel using the thumb plate or the plunger as the grip. Move the plunger at a speed of 100 mm/min. Increase the force to a maximum of 100 N or until the plunger is capable of delivering a second dose from the same syringe.

C.3.2 Using the test device (C.2.2), subject the syringe needle to a slowly increasing back pressure at approximately 100 kPa/min up to 300 kPa, and record whether the piston seal can be driven back in the syringe barrel.

C.4 Test report

The test report shall contain at least the following information:

a) the identity and nominal capacity of the syringe;

b) the maximum force applied;

c) the maximum pressure applied;

d) the date of testing.

Bibliography

[1] ISO 780:1997, *Packaging — Pictorial marking for handling of goods*

[2] ISO 7000:2004, *Graphical symbols for use on equipment — Index and synopsis*

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