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

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 7886-3 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*

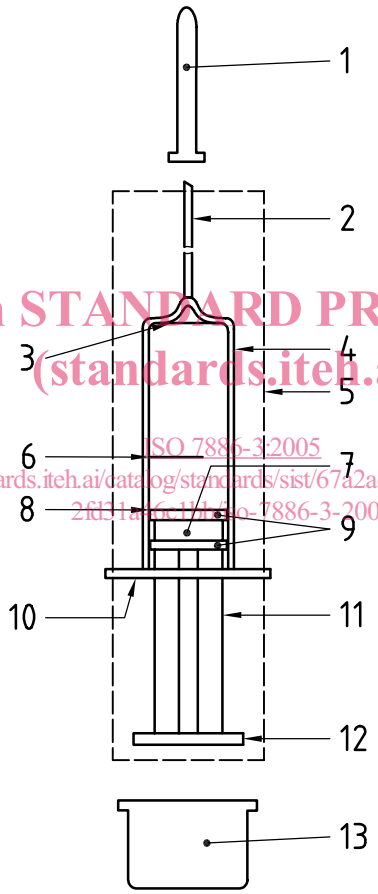
3 Terms and definitions

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.