INTERNATIONAL STANDARD

**ISO 7886-2**

First edition
1996-05-15

# Sterile hypodermic syringes for single use —

# Part 2:
Syringes for use with power-driven syringe pumps

*Seringues hypodermiques stériles, non réutilisables —*

*Partie 2: Seringues pour pousse-seringues mûs par un moteur*


Reference number
ISO 7886-2:1996(E)

# Contents





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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.

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 7886-2 was prepared by Technical Committee ISO/TC 84, *Medical devices for injections*, 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*

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

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.

# Introduction

## 1 General

In the preparation of this part of ISO 7886, it was recognized at an early stage that the absolute criterion of performance is achieved by the combination of the power-driven syringe pump and the syringe working as a complete system. The dependence of one element of the system on the performance of the other is a key factor. It is essential for the manufacturer of one of these components to liaise with the manufacturer of the other when considering changes in design, in order to ensure satisfactory operation of the system. In particular, when requested by a pump manufacturer, a syringe manufacturer should give information on tolerances and relationships between the syringe dimensions specified in this part of ISO 7886 and on performance characteristics, such as force to move the plunger, and the variations which might be expected.

## 2 Design criteria

The use of syringes which were initially designed and used as manually-operated devices in syringe pumps now makes it desirable to achieve much tighter tolerances on syringe dimensions than normally required for manual use.

It is understood that the degree of investment worldwide by all syringe manufacturers in moulding and manufacturing equipment is such that a change such as modifying diameters of push-buttons or the barrel inside diameter is largely out of reach of the syringe industry.

Typically the hard height of a syringe has never been regarded as a particularly critical dimension. Its tolerances are ordinarily relatively loose. The hard-height dimension is a function of not only the total length of plunger rod and the barrel, but also the thickness of the piston and finger grips. The piston thickness, by virtue of its relatively unsophisticated manufacturing process, can vary considerably. Because all these components are manufactured in multicavity moulds from many moulds around the world, the cumulative extreme tolerance buildup from cavity to cavity and mould to mould and location to location is such that these previously noncritical dimensions cannot be instantly tightened.

## 3 Syringe identification

It is important that when a syringe is fitted to a syringe pump, the pump is correctly programmed to perform satisfactorily with the particular syringe installed.

In view of the consequences of incorrect syringe identification by the pump, the need for an automatic system is recognized. Methods already in

use, such as mechanical sensing of the syringe outside diameter, are not deemed feasible in the long term. This is due to overlapping ranges of diameter of syringes produced by different manufacturers, and the lack of relationship between the outside and inside diameters of a syringe. It is also recognized that standardization of syringe barrel diameters across the industry is not a realistic option.

A means by which the pump could automatically identify the syringe model and use this to programme such information as barrel inside diameter, plunger force and occlusion alarm settings is seen as the next stage of this part of ISO 7886. A possible method of recognition is to identify the syringe and nominal capacity by means of a marking code on the barrel, printed at the same time as the syringe scale, and to use this to programme the pump automatically. It is recommended that development of such a system be worked on as soon as possible.

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# Sterile hypodermic syringes for single use —

# Part 2:
Syringes for use with power-driven syringe pumps

## 1 Scope

This part of ISO 7886 specifies requirements for sterile single-use hypodermic syringes of nominal capacity 5 ml and above, made of plastics materials and intended for use with power-driven syringe pumps.

This part of ISO 7886 does not apply to syringes for use with insulin (specified in ISO 8537), single-use syringes made of glass (specified in ISO 595), syringes prefilled with the injection by the manufacturer and syringes supplied with the injection as a kit for filling by a pharmacist. It does not address compatibility with injection fluids.

## 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 594-2:1990, *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 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 8601:1988, *Data elements and interchange formats — Information interchange — Representation of dates and times.*

IEC 601-2-24:—[1], *Medical electrical equipment — Part 2: Particular requirements for safety of infusion pumps and controllers.*

## 3 Definitions

For the purposes of this part of ISO 7886, the definitions given in ISO 7886-1 apply.

## 4 Nomenclature

Clause 4 of ISO 7886-1:1993 shall apply.

## 5 Cleanliness

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

## 6 Limits for acidity or alkalinity

Clause 6 of ISO 7886-1:1993 shall apply.

1) To be published.

## 7 Limits for extractable metals

Clause 7 of ISO 7886-1:1993 shall apply.

## 8 Lubricant

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

## 9 Tolerance on graduated capacity

Clause 9 of ISO 7886-1:1993 shall apply.

## 10 Graduated scale

Clause 10 of ISO 7886-1:1993 shall apply.

## 11 Syringe design

Critical dimensions for the fit of the syringe in a syringe pump shall be designated as shown in figure 1 and shall be as given in table 1.

All other dimensional and design requirements shall be as specified in ISO 7886-1.

The push-button should be of such a design as to inhibit neither the fit in a syringe pump driver mechanism designed to accept a flat push-button nor detection by a built-in detection device.

## 12 Piston/plunger assembly

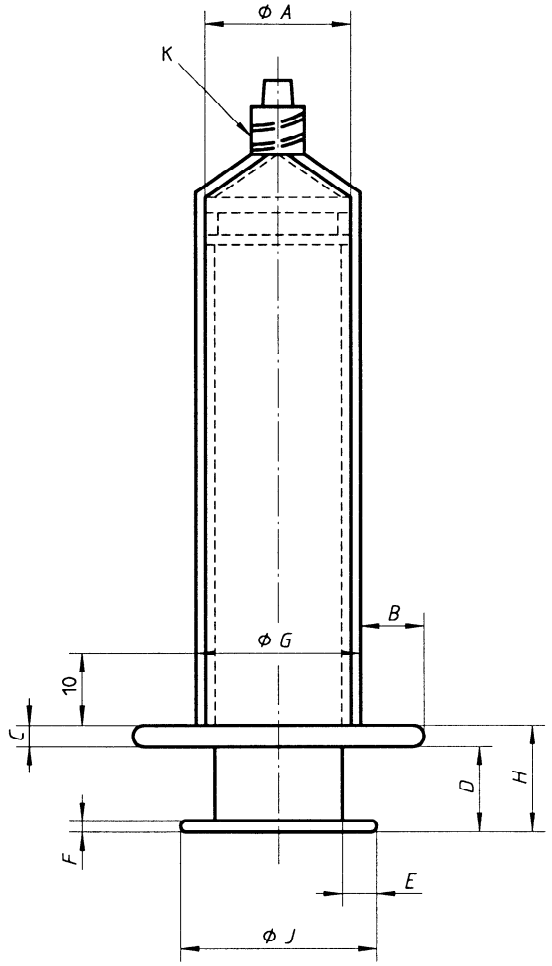
### 12.1 Design

The components of the syringe should be designed in such a manner that it is not possible easily to withdraw the plunger completely from the barrel.

**Table 1**

| Nominal capacity | Syringe dimensions | | | | | |
|---|---|---|---|---|---|---|
| | Tolerance on A | B min. | C max. | D min. | E min. | F max. |
| ml | ± % | mm | mm | mm | mm | mm |
| ⩾ 5 and < 10 | 1 | 4 | 3 | 10 | 2 | 3 |
| ⩾ 10 and < 20 | 1 | 4 | 3 | 10 | 2 | 3 |
| ⩾ 20 and < 30 | 1 | 4 | 3 | 10 | 2 | 4 |
| ⩾ 30 and < 50 | 0,5 | 4 | 3,5 | 10 | 2 | 4 |
| ⩾ 50 | 0,5 | 4 | 3,5 | 10 | 2 | 4 |

Dimensions in millimetres




*A* Mean inside diameter of the barrel over the swept volume.

*B* Distance of the projection of the finger grips from the outside surface of the barrel.

*C* Thickness of the finger grips.

NOTE — The finger grips should not be tapered.

*D* Distance from the surface of the finger grips nearer to the push-button to the surface of the push-button further from the finger grips when the fiducial line of the piston coincides with the zero line of the scale.

*E* Projection of the push-button beyond the outer dimension of the plunger ribs.

*F* Overall thickness of the push-button (including ribs, etc., if present).

*G* Outside diameter of the barrel measured at a distance of 10 mm from the underside of the finger grips.

*H* Hard height ($C + D$).

*J* Diameter of push-button.

K Luer lock fitting.

**Figure 1 — Designation of dimensions**

### 12.2 Fit of the piston in the barrel

Subclause 12.2 of ISO 7886-1:1993 shall apply.

The fit of the piston on the plunger should be such that relative axial movement between the two is kept to a minimum in order to reduce the possibility of siphoning.

## 13 Nozzle

### 13.1 Conical fitting

The male conical fitting of the syringe nozzle shall be in accordance with ISO 594-1 and shall have a locking fitting in accordance with ISO 594-2.

### 13.2 Nozzle lumen

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

## 14 Performance

### 14.1 Dead space

Subclause 14.1 of ISO 7886-1:1993 shall apply.

### 14.2 Freedom from air and liquid leakage past the piston

Subclause 14.2 of ISO 7886-1:1993 shall apply.

### 14.3 Flow characteristics

**14.3.1** When tested as described in annex A at a flowrate of 1 ml/h, the maximum time lag from initiating plunger push-button movement to achieving a steady flowrate of at least 95 % of the set flowrate shall not exceed 10 min.

**14.3.2** When tested as described in annex A, the overall percentage error of the flow/set delivery rate shall not exceed ± 2 % at both the flowrates given in A.4.

**14.3.3** When tested as described in annex A, the maximum variation in flowrate when measured at two observation-time windows shall be as shown in table 2 at both the flowrates given in A.4.

### 14.4 Compliance of syringe

When tested as described in annex B, the maximum displacement of fluid shall be as given in table 3.

**Table 2**

| Observation-time window<br>min | Maximum variation in flowrate<br>% |
|---|---|
| 2 | ± 5 |
| 5 | ± 2 |

**Table 3**

| Maximum displacement of fluid<br>ml | | | | | |
|---|---|---|---|---|---|
| Syringe nominal capacity<br>ml | Test pressure<br>kPa[1] | | | | |
| | 7 | 40 | 70 | 90 | 133 |
| ⩾ 5 and < 10 | 0,03 | 0,1 | 0,15 | 0,2 | 0,25 |
| ⩾ 10 and < 20 | 0,1 | 0,2 | 0,3 | 0,35 | 0,4 |
| ⩾ 20 and < 30 | 0,1 | 0,4 | 0,6 | 0,8 | 0,9 |
| ⩾ 30 and < 50 | 0,1 | 0,4 | 0,6 | 0,8 | 0,9 |
| ⩾ 50 | 0,4 | 1,2 | 1,5 | 1,8 | 2,1 |

1) 1 kPa = 7,5 $mmH_2O$ (approx.) = 0,145 $lbf/in^2$ (p.s.i.) (approx.).

### 14.5 Plunger movement forces

When tested as described in annex C, the maximum force (inclusive of any variation) required to initiate movement of the piston, the maximum sustaining force and the maximum allowable variation of the sustaining force shall be as given in table 4.

**Table 4**

| Flowrate<br>ml/h | Piston movement forces | | |
|---|---|---|---|
| | Force to initiate movement<br>N[1] | Sustaining force, max.<br>N | Total variation in sustaining force, max.<br>% |
| 1 | 30 | 20 | 20 |
| 5 | 30 | 15 | 15 |
| 99,9 | 30 | 15 | 10 |

1) 1 N = 0,224 lbf (approx.).

## 15 Packaging

### 15.1 Primary container

Each syringe shall be sealed in a primary container.

The materials of the container should not have detrimental effects on the contents, and 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 normal handling, transit and storage.

NOTE — 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 in accordance with ISO 7886-1 and with the following information:

a) the statement "Suitable for use with power-driven syringe pumps" or equivalent;

b) the model identification, if a manufacturer offers more than one product of the same nominal capacity.

### 16.2 Secondary container

The secondary container shall be marked in accordance with ISO 7886-1 and with the information listed in 16.1 a) and b).

### 16.3 Storage container

If a storage container is used, subclause 16.3 of ISO 7886-1:1993 shall apply.

The storage container shall be marked with the statement "Suitable for use with power-driven syringe pumps" or equivalent.

### 16.4 Transport wrapping

Subclause 16.4 of ISO 7886-1:1993 shall apply.

### 16.5 Syringe barrel

The syringe barrel shall be marked with:

a) the manufacturer's name or logo;

b) the model identification, if a manufacturer offers more than one product of the same nominal capacity.

# Annex A
(normative)

# Determination of flow characteristics

## A.1 Principle

Flow characteristics of the syringe (i.e. the time taken to achieve a steady flowrate, the overall percentage error of the flow/set delivery rate and the maximum variation in flowrate) are determined by measuring the flowrate produced by the use of a reference syringe driver.

## A.2 General requirements

**A.2.1** Perform tests as described in subclause 50.4 of IEC 601-2-24.

**A.2.2** Perform tests at a temperature constant to ± 1 °C, preferably (20 ± 1) °C. If tests are performed at a different constant temperature, correct the results to 20 °C.

**A.2.3** Equilibrate the syringe, distilled water and apparatus at the chosen test temperature for 4 h before testing.

## A.3 Apparatus

**A.3.1 Reference syringe driver,** having the following characteristics:

a) constant long-term linear drive accuracy equal to or better than ± 0,1 % of set drive rate, measured over a period of 60 min at drive rates essentially equivalent to flowrates of 1 ml/h, 5 ml/h and 100 ml/h;

   NOTE — Actual linear drive rates should be determined for all relevant syringe nominal capacities and brands to achieve flowrates closely approximating those specified.

b) short-term variation in drive accuracy as follows:

   1) any 1-min period: equal to or better than ± 0,5 % of mean drive rate.

   2) any 2-min period: equal to or better than ± 0,25 % of mean drive rate.

   3) any period of ⩾ 5 min: equal to or better than ± 0,1 % of mean drive rate.

c) capable of accepting syringes of the nominal capacities specified in this part of ISO 7886 and providing appropriate clamping of barrel and push-button (both sides) in accordance with the dimensions of these components specified in this part of ISO 7886.

**A.3.2 Distilled water,** complying with grade 3 of ISO 3696.

**A.3.3 Test rig,** as shown in figure A.1.

## A.4 Procedure

### A.4.1 Time lag to achieve steady flowrate

**A.4.1.1** Fill the syringe with distilled water (A.3.2) to beyond its nominal capacity. Invert the syringe so that the nozzle lumen is uppermost and depress the plunger to eject any air bubbles in the syringe. Attach the extension set shown in figure A.1 and the 1,2 mm (18G) needle.

**A.4.1.2** Mount the syringe in the test driver (A.3.1) as shown in figure A.1.

**A.4.1.3** Prime the line by running the test driver at a fairly high rate until drops of water appear steadily at the end of the needle and the fiducial line of the plunger is at the nominal capacity mark of the syringe. Turn off the drive.

**A.4.1.4** Fill the beaker on the balance pan with a small volume of distilled water and pour in approximately 10 ml of colourless heavy liquid paraffin to form a layer preventing evaporative loss.

Suspend the needle over the beaker (without mechanical contact with the balance) and position the tip of the needle so that it is below the paraffin layer but just inside the water layer without touching any part of the beaker.

**A.4.1.5** Allow the balance to stabilize for 5 min and when it has stabilized, tare it.

NOTES

1 The balance should be tared just prior to starting the equipment, because the tare cycle takes a finite time and the balance has to settle prior to starting the test.

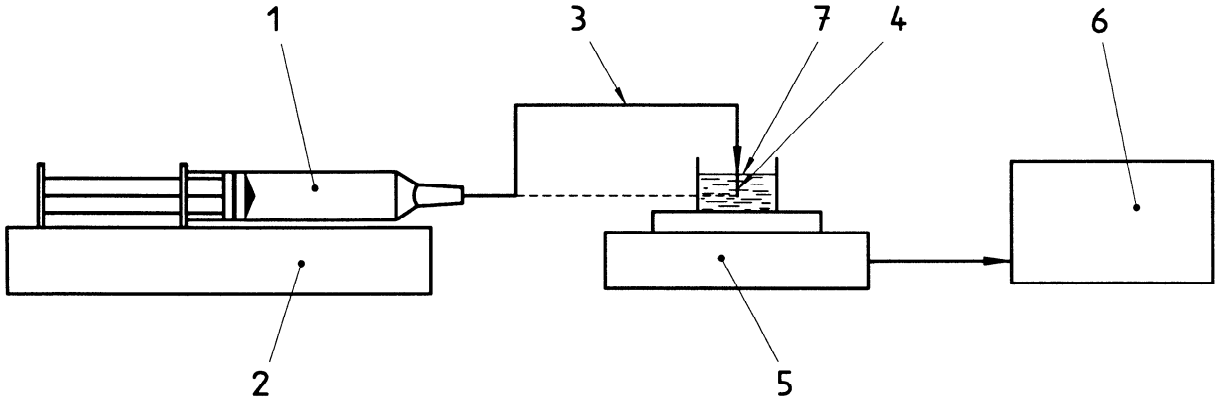
2 The electronic balance shown in figure A.1 should be placed on an antivibration mount and be protected from shock, vibration and draughts. The temperature should be controlled during the tests as specified in A.2.2.

**A.4.1.6** Set the test driver to a rate equivalent to a flowrate of 1 ml/h in the syringe under test. Set the sampling interval of the computer to 0,5 min.

**A.4.1.7** Switch on the drive and begin the test period at this instant. Allow the test to continue for a period of 2 h.

**A.4.1.8** Compute the flowrate at 0,5-min successive intervals and plot the flowrate in ml/h against time, in minutes, with a solid line on the graph (see A.4.4.1). Mark the 1 ml/h set flowrate on the graph using a dotted line (see figure A.2).

**A.4.1.9** Determine the time taken from the instant of start-up to achieve a steady flowrate by recording the time to reach 95 % of the set flowrate (see 14.3.1).




1 Syringe under test
2 Reference syringe driver (see A.3.1)
3 Administration set (1,2 mm i.d. × 1 m polyethylene tubing)
4 Needle [1,2 mm (18G) × approximately 10 cm length]
5 Electronic balance, accurate to four decimal places
6 Digital computer
7 Constant liquid level

**Figure A.1 — Test apparatus for determination of flowrate characteristics**

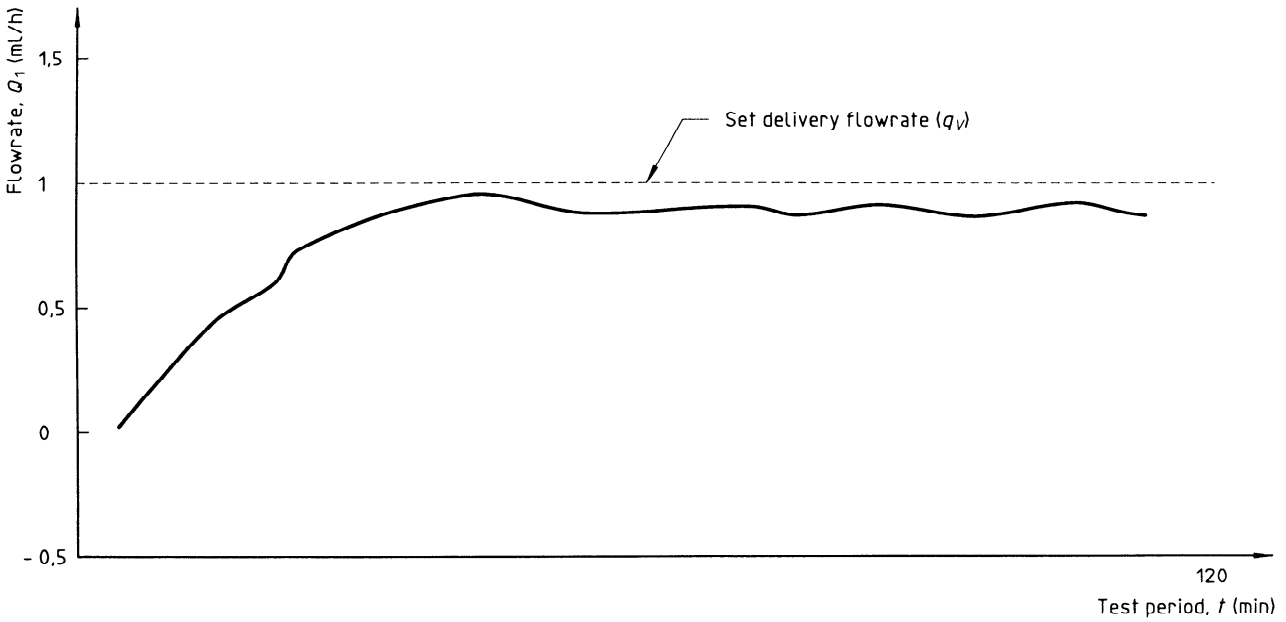



**Figure A.2 — Example of data gathered during first two hours of test**

### A.4.2 Overall percentage flowrate error

**A.4.2.1** Repeat the test in A.4.1 at drive rates equivalent to a flowrate of 2,5 ml/h for syringes of nominal capacity of 5 ml, and to 5 ml/h for all other nominal capacities.

**A.4.2.2** Determine the overall percentage flowrate error during the second hour of the test (see A.4.4 for calculations).

### A.4.3 Maximum variation in flow

Determine the maximum percentage variation in flowrate during the second hour of the test computed from the data obtained in the test of A.4.2.1 (see A.4.4 for calculations). Plot the percentage variation in flowrate against observation-time window as illustrated in figure A.3.

### A.4.4 Calculation of results

**A.4.4.1** Calculate the actual flowrate $Q_i$, in millilitres per hour, for each sampling interval for the first 120 min of the test period using equation (1).

$$Q_i = \frac{60\,(m_i - m_{i-1})}{t\rho} \qquad \ldots (1)$$

where

$i$ is the 1, 2, .., $t/t_s$;

$m$ is the total mass, expressed in grams (corrected for evaporative loss);

$m_i$ is the $i$th sample mass, expressed in grams, from the analysis period $t$ (corrected for evaporative loss);

$t$ is the analysis period, expressed in minutes (60 min);

$t_s$ is the sampling interval, expressed in minutes (0,5 min);

$\rho$ is the density of water (0,998 g/ml at 20 °C).

**A.4.4.2** Calculate $E_{p(max)}$ and $E_{p(min)}$ for the 2-min and 5-min observation-time windows using equations (2) and (3) respectively, over the analysis period $t_1$ (minutes) of the second hour of the test period.

Calculate $E_{p(max)}$ and $E_{p(min)}$ using the trumpet algorithm as follows:

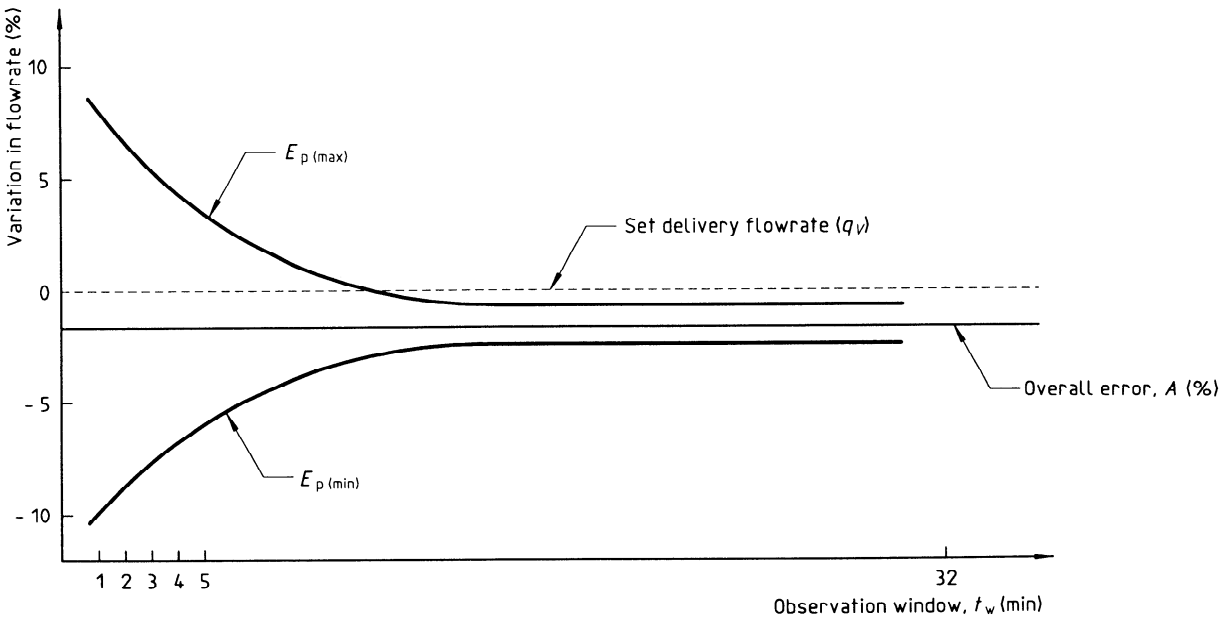



**Figure A.3 — Example of plot of data gathered during second hour of test**

For observation windows of duration $t_w$ = 2 min and 5 min, within the analysis period $t$, there are a maximum of $n$ observation windows, such that:

$$n = \frac{(t - t_w)}{t_s} + 1$$

where

$n$ is the maximum number of observation windows;

$t_w$ is the observation window duration, expressed in minutes;

$t_s$ is the sampling interval, expressed in minutes (0,5 min).

The maximum $E_{p(max)}$ and minimum $E_{p(min)}$ percentage variations within an observation window of duration period $t_w$ minutes are given by:

$$E_{p(max)} = \underset{j=1}{\overset{n}{\mathrm{MAX}}} \left[ \frac{t_s}{t_w} \cdot \sum_{i=j}^{j+t_w/t_s-1} \frac{Q_i - q_V}{q_V} (100) \right] \quad \ldots (2)$$

$$E_{p(min)} = \underset{j=1}{\overset{n}{\mathrm{MIN}}} \left[ \frac{t_s}{t_w} \cdot \sum_{i=j}^{j+t_w/t_s-1} \frac{Q_i - q_V}{q_V} (100) \right] \quad \ldots (3)$$

$$Q_i = \frac{60\,(m_i - m_{i-1})}{t_s \rho}$$

where

$m_i$ is the $i$th sample mass, expressed in grams, from the analysis period $t$ (corrected for evaporative loss);

$q_V$ is the set flowrate, expressed in millilitres;

$t_s$ is the sampling interval, expressed in minutes;

$t_w$ is the observation window duration, expressed in minutes;

$\rho$ is the density of water (0,998 g/ml at 20 °C).

**A.4.4.3** Calculate the overall mean percentage flowrate error $A$ using the following expression where $A$ is measured over the analysis period $t_1$ (the second hour of the test period):

$$A = \frac{100\,(Q - q_V)}{q_V} \quad (\%) \quad \ldots (4)$$

$$Q = \frac{60\,(m_j - m_k)}{t_1 \rho} \quad (\text{ml/h})$$

where

$q_V$ is the set flowrate, expressed in millilitres per hour;

$m$ is the total mass (corrected for evaporative loss), expressed in grams;

$m_j$ is the sample mass, expressed in grams, at the end of analysis period $t_1$ (where $j$ = 240);

$m_k$ is the sample mass, expressed in grams, at the start of analysis period $t_1$ (where $k$ = 120);

$\rho$ is the density of water (0,998 g/ml at 20 °C).

**A.4.4.4** Plot the following graphs using a linear scale with scale ratios as follows:

where

$q_V$ is the set flowrate.

For the start-up graph, the flowrate axis shall show:

maximum = $2q_V$

minimum = $-0{,}2q_V$

scale increment = $0{,}2q_V$

time = 0 min – 120 min (10-min intervals)

For the trumpet graph, the flowrate axis shall show:

maximum = 15 %

minimum = −15 %

scale increment = 5 %

time = 0 min – 31 min (1-min intervals)

Plot flowrate $Q_i$ (ml/h) against time $t$ (minutes) for the first two hours of the test period (see example in figure A.2). Indicate the set flowrate by means of a broken line. Indicate flowrate $Q_i$ by means of a solid line.

Plot percentage variation $E_{p(max)}$ and $E_{p(min)}$ against observation window duration $t_w$ (minutes) and the overall mean percentage error $A$ [derived from equation (4)] measured over the analysis period $t_1$ (minutes) of the second hour of the test period (see example in figure A.3).

Indicate $E_{p(max)}$ and $E_{p(min)}$ and the overall mean percentage flowrate error $A$ by means of a solid line.

Indicate the zero error by means of a dotted line.

## A.5 Test report

The test report shall include at least the following information:

a) the identity of the syringe;

b) the time, in minutes, taken to achieve a steady flowrate;

c) the overall percentage flowrate error;

d) the maximum variation in flowrate at 2-min and 5-min observation windows.

# Annex B
(normative)

# Determination of compliance of syringe

## B.1 Principle

The compliance of the syringe (i.e. the amount by which the nominal capacity of the syringe changes when an internal hydraulic pressure is applied) is measured by recording the volume of liquid introduced into a full syringe in order to generate specified hydraulic pressures within the syringe.

## B.2 Apparatus

**B.2.1 Test apparatus,** as shown in figure B.1. For syringes under test of nominal capacity less than 50 ml, use a 1-ml pressurizing syringe. For syringes under test of nominal capacity 50 ml and above, use a 5-ml pressurizing syringe.

**B.2.2 Distilled water,** complying with grade 3 of ISO 3696.

## B.3 Procedure

**B.3.1** Purge the syringe under test and fill it to its nominal capacity with distilled water (B.2.2). Ensure that all air is excluded from the system.

**B.3.2** Connect the syringe under test to the test apparatus (B.2.1) and rigidly clamp the plunger so that it cannot be moved within the barrel.

**B.3.3** By means of the three-way valve, isolate the syringe under test from the pressurizing syringe and the pressure gauge.

**B.3.4** Use the pressurizing syringe to exert in turn the test pressures in the fluid system given in table 3.

**B.3.5** Note the maximum volume displaced in the pressurizing syringe to achieve each of the test pressures.

**B.3.6** By means of the three-way valve, connect the syringe under test to the pressurizing syringe and the pressure gauge.

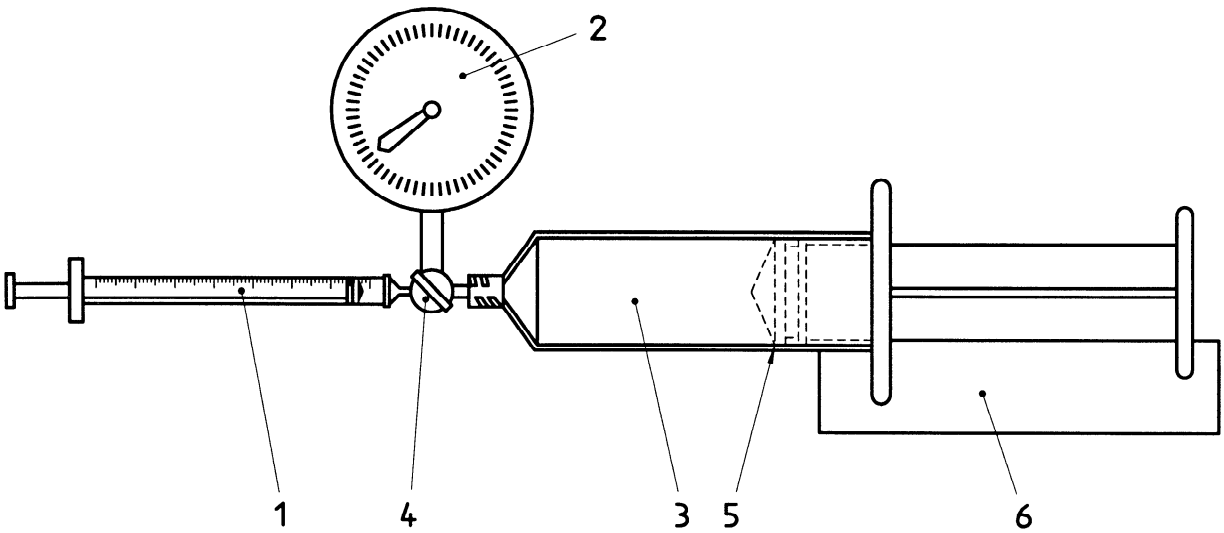
**B.3.7** Repeat B.3.4 and B.3.5. Calculate the difference between the volumes recorded in B.3.5 and B.3.7 for each test pressure and record it as the compliance of the syringe under test at that pressure.

## B.4 Test report

The test report shall include at least the following information:

a) the identity of the syringe;

b) the volumes recorded in B.3.7 for each test pressure.




1 Pressurizing syringe with fine graduations
2 Pressure gauge
3 Syringe under test
4 Three-way valve
5 Nominal capacity mark
6 Securing clamp

**Figure B.1 — Apparatus for determination of compliance**

# Annex C
(normative)

# Determination of forces required to move the piston

## C.1 Principle

A mechanical testing machine is used to expel water while the force to move the piston is being recorded.

## C.2 Apparatus

**C.2.1 Mechanical testing machine,** as shown in figure C.1, capable of attachment to the syringe under test and of depressing the syringe piston at a constant linear rate, while at the same time continuously measuring and recording the force with an accuracy of 1 % of full-scale reading.

**C.2.2 Distilled water,** complying with grade 3 of ISO 3696.

## C.3 Procedure

**C.3.1** Record the position of the piston seal in the barrel.

**C.3.2** Fill the syringe with water (C.2.2) to beyond the nominal capacity.

**C.3.3** Attach the administration set and needle as shown in figure C.1.

**C.3.4** Expel water until the fiducial line of the piston is at the nominal capacity mark of the syringe.

**C.3.5** Mount the syringe in the test fixture and clamp the push-button to the driving head of the mechanical testing machine (C.2.1).

**C.3.6** Set the translation speed of the piston to be equivalent to the desired volumetric flowrate.

**C.3.7** Wait 30 s.

**C.3.8** Start the testing machine.

**C.3.9** Measure and note the force required to initiate movement of the piston.

**C.3.10** Expel water for a period of 2 h, or until the syringe is empty, whichever is shorter.

**C.3.11** Plot the forces required to move the piston during the second half of the test period.

**C.3.12** For large syringes (i.e. greater than 30 ml nominal capacity) and at low flowrates (i.e. less than 5 ml/h), repeat C.3.2 to C.3.11 three times, with the fiducial line of the piston set at three different points along the syringe barrel, once for each setting.

## C.4 Calculation of results

For each flowrate, determine

a) the force required to initiate movement of the piston;

b) the maximum force ($F_{max}$) required to sustain movement of the piston. Disregard that portion of the trace that relates to the passage of the piston through the parking position;

c) the minimum force ($F_{min}$) required to sustain movement of the piston. Disregard that portion of the trace that relates to the passage of the piston through the parking position;

d) the range of forces ($F_{max} - F_{min}$);

e) the maximum total variation, expressed as a percentage, using the expression:

$$\frac{(F_{max} - F_{min})\,100}{F_{max}}$$

## C.5 Test report

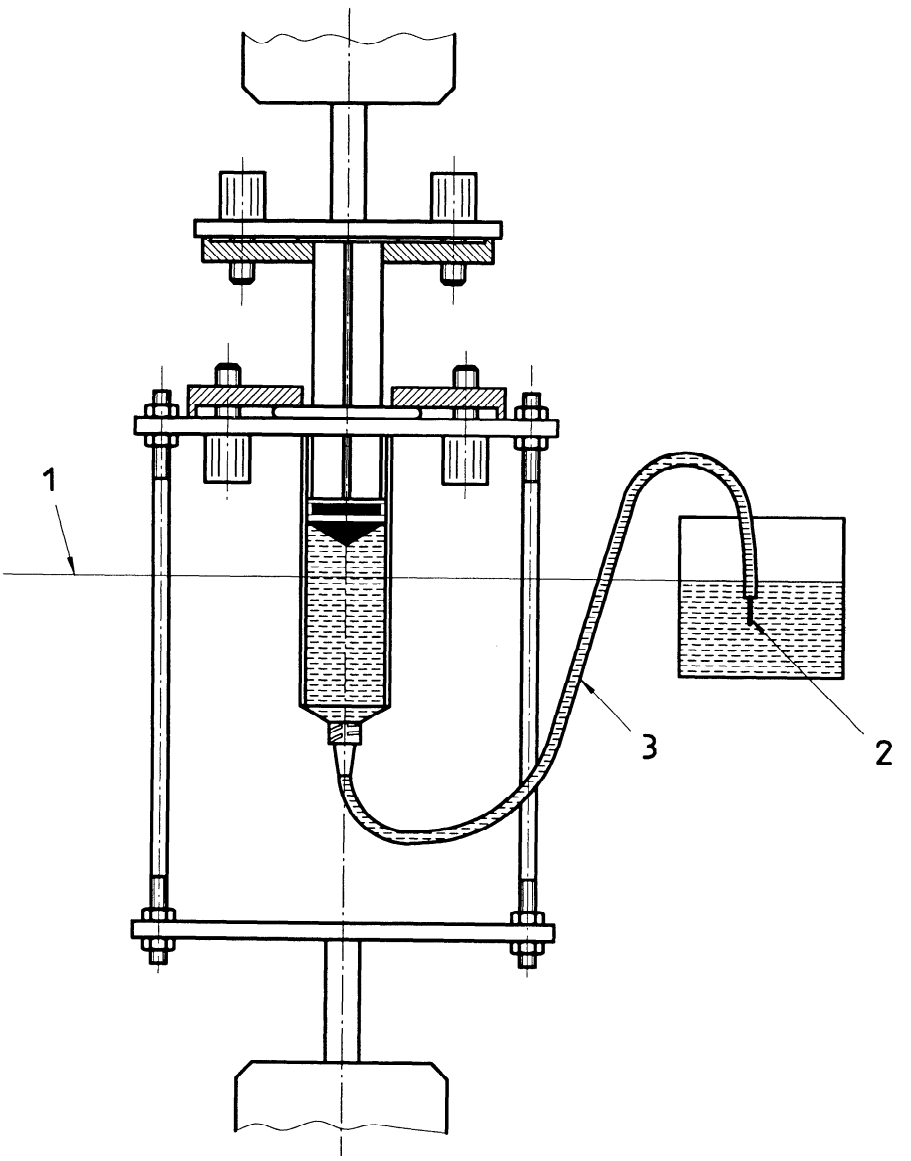
The test report shall include at least the following information:

a) the identity of the syringe;

b) the force required to initiate movement of the piston;

c) the minimum and maximum forces required to sustain movement of the piston;

d) the maximum total percentage variation of the sustaining force.




1 Water level adjusted graduation mark at 50 % of nominal capacity of syringe
2 Needle [1,2 mm (18G) × approximately 10 cm length]
3 Administration set (1,2 mm i.d. × 1 m polyethylene tubing)

**Figure C.1 — Apparatus for determination of force to move piston**

# Annex D
(informative)

# Rationale for flowrate characteristics

## D.1 Long-term accuracy

In order to comply with this part of ISO 7886, the overall percentage error of the flow/set delivery rate of the syringe tested is not to exceed ± 2 % when measured over a period of 1 h (see 14.3.2).

The test instrumentation is required to have an inherent accuracy at least one order of magnitude better than this, in order to keep measurement errors to a minimum. The accuracy required is therefore one-tenth of ± 2 % divided by a factor of 2, giving a specification of ± 0,1 %.

## D.2 Short-term accuracy

In order to comply with this part of ISO 7886, the maximum variation in flowrate is ± 5 % for a 2-min observation window and ± 2 % for a 5-min observation window (see 14.3.3). With experience of these measurements, it is reasonable to assume that the maximum allowable for a 1-min observation window would have been ± 10 %, although measurements will only be taken for the 2-min and 5-min windows.

Using the same philosophy as for long-term accuracy, the short-term accuracy required is as specified above. Note that accuracy has also been specified for observation windows greater than 5 min to ensure that there are no long cycles giving rise to excessive measurement errors.

## D.3 Feasibility of design

It is assumed that the reference syringe driver will be calibrated periodically and a certificate of accuracy provided. Design of such a device is regarded as being realistic, and the device could be calibrated using a remote (no-contact) linear measurement transducer of sufficient resolution.

# Annex E
(informative)

# Bibliography

[1] ISO 595-1:1986, *Reusable all-glass or metal-and-glass syringes for medical use — Part 1: Dimensions.*

[2] ISO 595-2:1987, *Reusable all-glass or metal-and-glass syringes for medical use — Part 2: Design, performance requirements and tests.*

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

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**ICS 11.040.20**

**Descriptors:** medical equipment, sterile equipment, disposable equipment, syringes, specifications, performance, dimensions, tests, packaging, labelling.

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