INTERNATIONAL STANDARD

ISO 7886-2

Second edition
2020-04

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 électriques

Reference number
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Foreword

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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 7886-2:1996), which has been technically revised. The main changes compared to the previous edition are as follows:

— Syringe sizes 1 ml to 5 ml were added to the scope of this document.

— Overall flow rate requirement was removed from Clause 14 as it is predominantly affected by the barrel inner diameter (ID), which is addressed in Clause 11.

— Pump test speeds were adjusted for each syringe size to better reflect the range of speeds used in general clinical settings.

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

0.1 General

In the preparation of this document, 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, a syringe manufacturer should give information on tolerances and relationships between the syringe dimensions specified in this document and on performance characteristics such as the force to move the plunger, and the variation which might be expected.

The selection of test speeds for flow rate accuracy recognized that low speeds are worse-case and result in large variation; however, selecting speeds of less than 1 ml/h was considered inappropriate due to limitations of the gravimetric test method error (due to factors such as balance stabilization and difficulty in measuring micro amounts of fluid using balances designed for static measurements).

It is recognized that start-up time and travel through parking position may impact pump forces and should be considered for exclusion, if necessary.

The syringe driver and measurement equipment characteristics might influence test method error; therefore, it is recommended to include the appropriate level of accuracy and precision of equipment and to perform test method validations.

0.2 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 molding and manufacturing equipment is such that a change such as modifying diameters of push-buttons or the barrel inner diameter (ID) 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 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 barrel flanges. The piston thickness, by virtue of its relatively unsophisticated manufacturing process, can vary considerably. Because all these components are manufactured in multi-cavity molds from many molds around the world, the cumulative extreme tolerance buildup from cavity to cavity and mold to mold and location to location is such that these previously noncritical dimensions cannot be instantly tightened.

0.3 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 outer diameter, are not deemed feasible in the long term to reduce errors in syringe identification. This is due to overlapping ranges of diameter of syringes produced by different manufacturers. It is also recognized that standardization of syringe barrel diameters (IDs) across the industry is not a realistic option.

A means by which the pump could automatically identify the syringe model and use this to program such information as barrel inner diameter (ID), plunger force and occlusion alarm settings is seen as the next stage of this standard. 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 program the pump automatically. It is recommended that development of such a system be worked on as soon as possible.

0.4 Infusion speeds and syringe size selection

The flow rates described in this document are for syringe tests and are not recommendations for clinical practice.

In general, as flow rate accuracy is dependent on linear travel of the plunger/pump driver, smaller size syringes tend to have a higher resolution and they also tend to have a higher flow rate accuracy at slower speeds.

Guidance on transition periods for implementing the requirements of this document is given in ISO/TR 19244[1].

Sterile hypodermic syringes for single use —

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

1 Scope

This document specifies requirements for sterile single-use hypodermic syringes of nominal capacity 1 ml and above, made of plastic materials and intended for use with power-driven syringe pumps.

This document does not apply to syringes with auto-disable syringe features (ISO 7886-3[2]), syringes for use with insulin (ISO 8537[3]), single-use syringes made of glass, 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 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 7886-1:2017, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7886-1, ISO/IEC Guide 99 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
parking position
location in the barrel where the plunger stopper is positioned before the user opens the packaging

4 Nomenclature

The requirements specified in ISO 7886-1:2017, Clause 4 apply.

5 General requirements

The requirements specified in ISO 7886-1:2017, Clause 5 apply.

6 Limits for acidity or alkalinity

The requirements specified in ISO 7886-1:2017, 6.2 apply.

7 Limits for extractable metals

The requirements specified in ISO 7886-1:2017, 6.3 apply.

8 Lubricant

The requirements specified in ISO 7886-1:2017, Clause 7 apply.

9 Tolerance on graduated capacity

The requirements specified in ISO 7886-1:2017, Clause 8 apply.

10 Graduated scale

The requirements specified in ISO 7886-1:2017, Clause 9 apply.

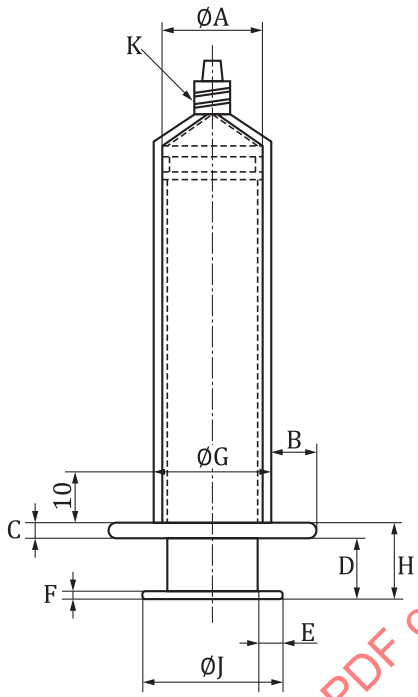
11 Syringe design

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.

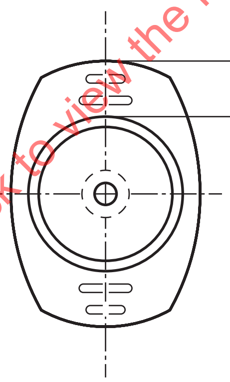
Table 1 — Syringe dimensions critical to volume and flow accuracy

Nominal capacity, *V* ml	Syringe dimensions					
	Tolerance on ØA ±%	B min. mm	C max. mm	D min. mm	E min. mm	F max. mm
1 ≤ *V* < 2	2	4	3	10	2	3
2 ≤ *V* < 5	1	4	3	10	2	3
5 ≤ *V* < 10	1	4	3	10	2	3
10 ≤ *V* < 20	1	4	3	10	2	3
20 ≤ *V* < 30	1	4	3	10	2	4
30 ≤ *V* < 50	0,5	4	3,5	10	2	4
V ≥50	0,5	4	3,5	10	2	4

Dimensions in millimetres



a) **Side view**



b) **Top view**

Key

A mean inner diameter of the barrel over the swept volume

B distance of the projection of the barrel flanges from the outside surface of the barrel

C thickness of the barrel flanges

D distance from the surface of the barrel flanges nearer to the push-button to the surface of the push-button further from the barrel flanges 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 barrel flanges

H hard height (C + D)

J diameter of push-button

K luer lock fitting

Figure 1 — Designation of dimensions

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

The design of the push-button should be such that it does not inhibit the fit in a syringe pump driver mechanism designed to accept a flat push-button and it does not inhibit the detection by a built-in detection device. The barrel flanges [see Figure 1 a)] should not be tapered.

The fit of the plunger stopper 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 free flow or siphoning.

12 Piston/plunger assembly

12.1 Design

The requirements specified in ISO 7886-1:2017, 11.1 apply.

12.2 Fit of plunger stopper/plunger in barrel

The requirements specified in ISO 7886-1:2017, 13.4 apply.

13 Nozzle

13.1 Conical fitting

The male conical fitting of the syringe nozzle shall be in accordance with ISO 80369-7 and shall have a locking fitting in accordance with ISO 80369-7.

13.2 Nozzle lumen

The requirements specified in ISO 7886-1:2017, 12.3 apply.

14 Performance

14.1 Dead space

The requirements specified in ISO 7886-1:2017, 13.1 apply.

14.2 Freedom from air and liquid leakage past the plunger stopper

The requirements specified in ISO 7886-1:2017, 13.2 apply.

14.3 Short-term flow rate error

When tested as described in Annex A, the flow rates, start-up time (exclusion time) and analysis period shall be as shown in Table 2.

Table 2 — Flow rates specifications

Nominal capacity of syringe, V ml	Flow rates ml/h	Start-up time min	Analysis period min
$1 \leq V < 2$	1	10	50 minus parking position
$2 \leq V < 10$	1	30	60 minus parking position

Table 2 *(continued)*

Nominal capacity of syringe, *V* ml	**Flow rates** ml/h	**Start-up time** min	**Analysis period** min
10 ≤ *V*	5	30	60 minus parking position

The maximum permissible error in flow rate when measured in two observation-time windows shall be as shown in Table 3.

Table 3 — Maximum permissible flow rate error

Observation window min	**Nominal capacity of syringe, *V*** ml	**Maximum error in flow rate** %
2	All nominal capacities of syringes	±5
5	1 ≤ *V* < 10	±5
	10 ≤ *V*	±4
NOTE The allowed error on expelled volume from the syringe as defined in ISO 7886-1:2017, Table 1 was used as a basis for calculation of the allowed flow rate error for the 5 min window.		

14.4 Pump forces

Syringe manufacturers should perform pump force characterization and make available to pump manufacturers for syringes which are indicated for use on pumps. Flow rates used for pump forces are listed in Table 4 and details for the method used to test each nominal capacity of syringe are given in Annex B.

Pump manufacturers should also perform the testing described in Annex B to ensure correct software programming. This data should be shared between pump and syringe manufacturers to ensure the correct regional product has been characterized for a given market.

Table 4 — Recommended flow rates for pump forces

Nominal capacity of syringe, *V* ml	**Flow rates** ml/h		
	Low	Medium	High
1 ≤ *V* < 2	0,5	2	5
2 ≤ *V* < 5	1	5	10
5 ≤ *V* < 10	5	10	25
10 ≤ *V* < 20	5	10	50
20 ≤ *V* < 30	0,5	25	50
30 ≤ *V* < 50	0,5	25	50
V ≥50	1	50	100
NOTE The flow rates are provided for syringe tests, not as recommendations for clinical practice.			

14.5 Syringe compliance

When tested as described in Annex C, the maximum displacement of fluid shall be within given values shown in Table 5.

Table 5 — Maximum allowable fluid displaced as a function of pressure

Syringe nominal capacity, *V* ml	Test pressure kPa[a]				
	≥7	≥40	≥70	≥90	≥133
	Maximum displacement volume ml				
1 ≤ *V* < 2	n/a	n/a	n/a	0,03	0,04
2 ≤ *V* < 5	n/a	0,05	0,08	0,11	0,13
5 ≤ *V* < 10	0,03	0,10	0,15	0,20	0,25
10 ≤ *V* < 20	0,10	0,20	0,30	0,35	0,40
20 ≤ *V* < 30	0,10	0,40	0,60	0,80	0,90
30 ≤ *V* < 50	0,10	0,40	0,60	0,80	0,90
V ≥50	0,40	1,20	1,50	1,80	2,10

[a] 1 kPa = ~7,5 mmHg = ~0,145 lbf/in^2 (psi).

15 Packaging

15.1 Unit packaging and self-contained syringe units

15.1.1 Unit packaging

The requirements specified in ISO 7886-1:2017, 14.1.1 apply.

15.1.2 Self-contained syringe units

The requirements specified in ISO 7886-1:2017, 14.1.2 apply.

15.2 Multiple unit pack

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

15.3 User packaging

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

16 Information supplied by the manufacturer

16.1 General

The requirements specified in ISO 7886-1:2017, 15.1 apply.

16.2 Syringes

16.2.1 General

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

In addition, the syringe barrel shall be marked with the following information:

a) the manufacturer's name or logo;

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

16.2.2 Additional marking for self-contained syringe units

The requirements specified in ISO 7886-1:2017, 15.2.2 apply.

16.3 Unit packaging

The requirements specified in ISO 7886-1:2017, 15.3 apply.

In addition, the unit packaging shall be marked with the following information:

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

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

16.4 Multiple unit packs

16.4.1 General

The requirements specified in ISO 7886-1:2017, 15.4.1 apply.

In addition, the multiple unit packs shall be marked with the following information:

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

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

16.4.2 Multiple unit packs with self-contained syringes

The requirements specified in ISO 7886-1:2017, 15.4.2 apply.

In addition, the multiple unit packs with self-contained syringes shall be marked with the following information:

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

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

16.5 User packaging

The requirements specified in ISO 7886-1:2017, 15.5 apply.

In addition, the user packaging shall be marked with the following information:

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

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

16.6 Storage container

The requirements specified in ISO 7886-1:2017, 15.6 apply.

In addition, the storage container shall be marked with the following information:

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

16.7 Transport wrapping

If a storage container is not used but the user containers are wrapped for transportation, the information required by 16.6 shall either be marked on the wrapping or shall be visible through the wrapping.

Annex A
(normative)

Short-term flow rate accuracy

A.1 Principle

Flow rate accuracy of the syringe is obtained by determining the flow rate of a reference syringe driver and assessing the collected data using an observation time window analysis.

A.2 General requirements

A.2.1 Perform tests at a constant temperature between 17 °C and 27 °C. During testing allowed temperature range is ±1 °C. The relative humidity should be between 45 % and 80 % to prevent evaporation. The thermometer shall have a resolution of 0,2 °C or better and the hygrometer shall have a resolution of 1 %. Both these instruments shall be calibrated.

A.2.2 Equilibrate the syringe, distilled water and apparatus at the chosen test temperature for at least 2 hours before testing.

Uncertainty can be determined by using the procedure described in EURAMET Calibration Guide 19[5] and ISO/IEC Guide 98-3[6].

A.3 Apparatus

A.3.1 **Syringe driver**, capable of accepting syringes of the nominal capacities specified in Table 2 and providing appropriate clamping of barrel and push-button (both sides) in accordance with the dimensions of these components specified in Table 1.

A.3.2 **Distilled water**, grade III in accordance with ISO 3696.

A.3.3 **Gravimetric test apparatus**, as shown in Figure A.1. All used instruments should be calibrated. The balance characteristics should be chosen according to the flow rate to be determined. In general, a balance with at least 0,01 mg resolution is recommended.

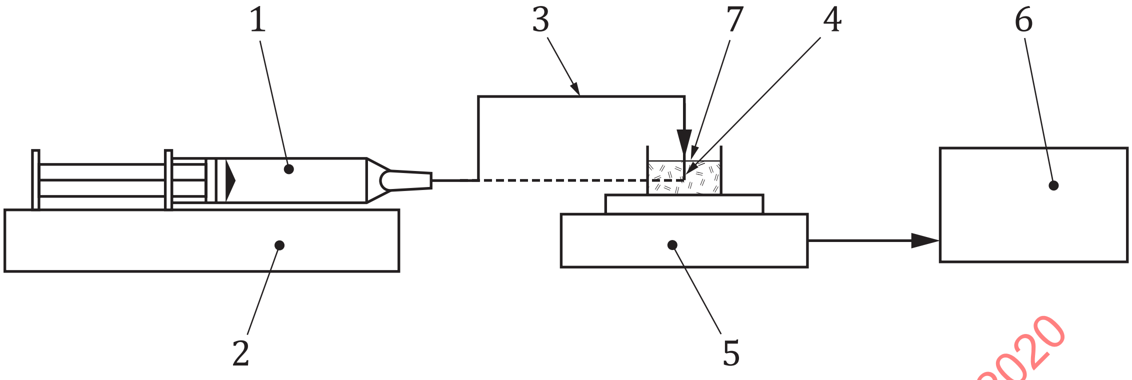
A.3.4 **Alternative equipment for measuring flow of fluid through the extension set**, such as flow sensors, may be applicable. It is recommended that alternative equipment accuracy is equivalent or better than the gravimetric test apparatus.

A.3.5 **Calibrated thermometer**, with a resolution equal or better than 0,1 °C should be used to measure the water temperature before filling the syringe at the end of the test. The average value should be used to determine the density of the liquid used in Formula (A.1).

A.4 Procedure

A.4.1 Measure the temperature of the distilled water and fill the syringe 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 and the 1,2 mm (18G) needle.

A.4.2 Mount the syringe in the syringe driver (A.3.1) as shown in Figure A.1.



Key

1 syringe under test

2 reference syringe driver (see A.3.1)

3 tubing ~1,02 mm (±0,1 mm) and 1 120 mm length [0,04" × 44"] with male and female Luer adapters at each end. Tygon and polyethylene are some examples of an acceptable, flexible tubing material for this application.

4 needle [1,2 mm (18G) and approximately 40 mm length]

5 electronic balance

6 digital computer

7 liquid level

Figure A.1 — Gravimetric test apparatus for determination of flow rate

A.4.3 Prime the line by running the syringe 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 driver.

A.4.4 Fill the beaker on the balance pan with a small volume of distilled water (A.3.2) and pour in sufficient amount of colourless heavy liquid paraffin to form a layer minimizing evaporative loss. An evaporation trap attached to the balance plate can also be used to minimize evaporation 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.

If necessary, the evaporation rate should be determined and used to correct the flow rate error.

A.4.5 Allow the balance to stabilize for 5 min.

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

A.4.6 Set the test driver to flow rate in accordance with Table 2. Set the sampling interval of the computer to 30 s.

A.4.7 Switch on the driver and begin the test period at this instant. Allow the test to continue for a period sufficient to include start-up time and analysis period in accordance with Table 2.

A.4.8 Calculate the actual volume flow rate, Q_i, in millilitres per hour, at 30 s successive intervals for the test period using Formula (A.1).

$$Q_i = \frac{60\left(m_i - m_{i-1}\right)}{t\rho} \tag{A.1}$$

where

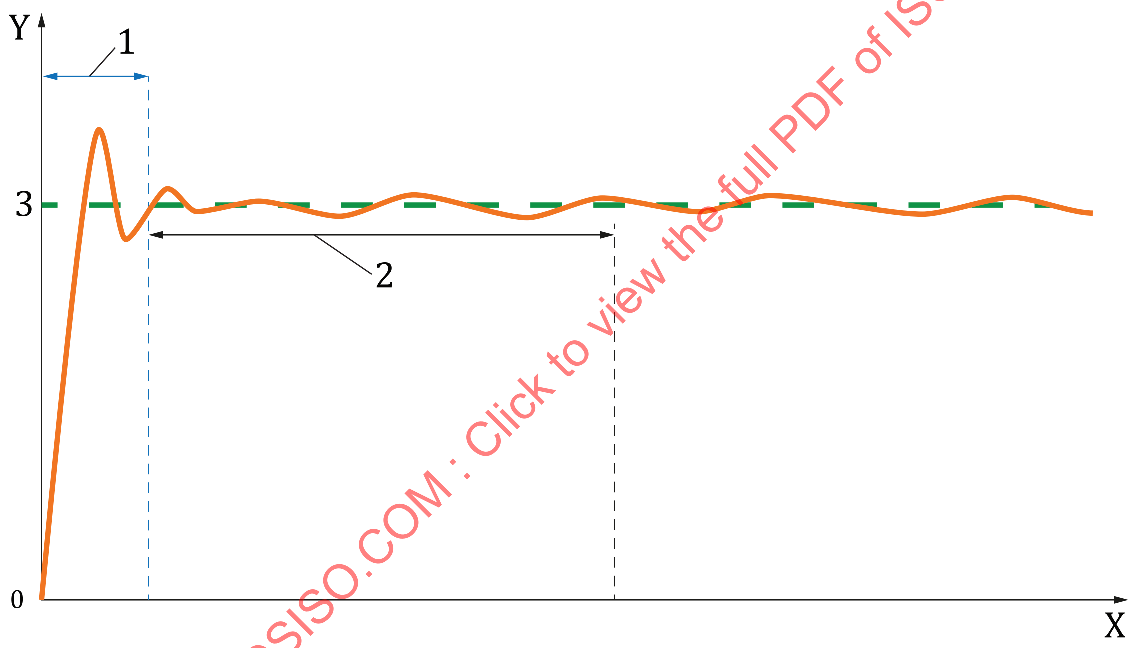
i is the 1, 2, ..., t/t_s;

$m_{i\text{-}1}$ is the initial mass, expressed in grams (corrected for evaporative loss and buoyancy);

m_1 is the final mass, expressed in grams (corrected for evaporative loss and buoyancy);

t is the analysis period, expressed in minutes;

ρ is the density of water at the test temperature determined according to Tanaka formula[6]



Key

X time (min)

Y flow rate (ml/h)

1 start-up time

2 flow rate analysis period

3 set flow rate

Figure A.2 — Example of typical flow rate analysis period

A.4.9 Start-up time to be excluded should be in accordance with Table 2. This allows time for the test system, including syringe driver, to travel sufficient distance in order to achieve steady state.

A.4.10 Disregard the portion of travel that relates to passage of the piston through the parking position.

A.5 Calculation of results

A.5.1 2 min and 5 min observation time window analysis

A.5.1.1 Perform the procedure as in A.4 at flow rate specified in Table 2.

A.5.1.2 Determine the maximum $E_{p(max)}$ and minimum $E_{p(min)}$ percentage error in flow rate in the analysis period, which excludes start-up time.

A.5.1.3 Calculate $E_{p(max)}$ and $E_{p(min)}$ for the 2 min and 5 min observation windows using Formula (A.3) and (A.4) respectively, over the analysis period, t_w (min).

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

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 as given in Formula (A.2):

$$n=\frac{(t-t_w)}{t_s}+1 \tag{A.2}$$

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 errors within an observation window of duration period t_w minutes are given by Formula (A.3):

$$E_p(\max)=\underset{j=1}{\overset{n}{MAX}}\left[\frac{t_s}{t_w}\cdot\sum_{i=j}^{j+1t_w/t_s-1}\frac{Q_i-q_v}{q_v}(100)\right] \tag{A.3}$$

where

m_i	is the i^{th} sample mass, expressed in grams, from the analysis period t (corrected for evaporative loss and buoyancy correction);
q_v	is the set flow rate, expressed in millilitres per hour;

$$E_p(\min)=\underset{j=1}{\overset{n}{MIN}}\left[\frac{t_s}{t_w}\cdot\sum_{i=j}^{j+1t_w/t_s-1}\frac{Q_i-q_v}{q_v}(100)\right] \tag{A.4}$$

where

t_s	is the sampling interval, expressed in minutes;
t_w	is the observation window duration, expressed in minutes;

$$Q_i = \frac{60(m_i - m_{i-1})}{t_s \rho} \qquad \text{(A.5)}$$

where

ρ is the density of water.

A.6 Test report

The test report shall include at least the following information for each of the two flow rates tested:

a) the identity and volume of the syringe;

b) a reference to this document, e,g. ISO 7886-2:2020;

c) observation window analysis: the maximum and minimum error in flow rate at 2 min and 5 min observation windows;

d) test temperature and relative humidity;

e) any deviations from the procedure;

f) any unusual features observed;

g) the date of test.

NOTE Optional, include a flow rate graph such as Figure A.2