Sterile Hypodermic Syringes for Single Use: Part1: Syringes for manual use DIN EN IS0 7886-1

Description

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. When tested in accordance with annex B , the piston shall not become detached from the plunger.

The plunger should be of a length adequate to allow the piston to traverse the full length of the barrel, but it should not be possible easily to withdraw the plunger completely from the barrel.

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 should be:

a)**8** mm for syringes of nominal capacity up to but excluding 2 ml;

b)9 mm for syringes of nominal capacity of 2 ml up to but excluding 5 ml;

c) 12,5 mm for syringes of nominal capacity of 5 mi and greater.

12.2 Fit of piston in barrel

When the syringe is filled with water and held verti cally with first one end and then the other end up permost, the plunger shall not move by reason of its own mass.

NOTE *5* **A** suggested test method and performance cri teria for the forces required to move the plunger are given

in annex G. It is recommended that this test be used to generate data on which to decide whether to make this test mandaton/ in a future revision of this part of IS0 7886.

12.3 Fiducial line

There shall be a visible and defined edge serving as the fiducial line at the end of the piston. The fiducial line shall be in contact with the inner surface of the barrel.

13 Nozzle

13.1 Conical fitting

The male conical fitting of the syringe nozzle shall be in accordance with IS0 594-1.

If the syringe has a locking fitting, it shall be in ac cordance with IS0 594-2.

13.2 Position of nozzle on end of barrel

13.2.1 On syringes of nominal capacity up to but not including 5 mi, the syringe nozzle shall be situated centrally, Â¡.e. it shall be coaxial with the barrel.

13.2.2 On syringes of nominal capacity 5 ml and greater, the syringe nozzle shall be situated either centrally or eccentrically.

13.2.3 If the syringe nozzle is eccentric, its axis shall be vertically below the axis of the barrel when the syringe is lying on a flat surface with the scale up permost. The distance between the axis of the nozzle and the nearest point on the internal surface of the bore of the barrel shall be not greater than 4,5 mm.

13.3 Nozzle lumen

The nozzle lumen shall have a diameter of not less than 1.2 mm.

14 Performance

14.1 Dead space

When tested in accordance with annex C, the volume of liquid contained in the barrel and the nozzle when the piston is fully inserted shall be as given in table 1,

14.2 Freedom from air and liquid leakage past piston

When tested in accordance with annex D, there shall be no leakage of water past the piston or seal(s).

When tested in accordance with annex B, there shall be no leakage of air past the piston or seal(s), and there shall be no fall in the manometer reading.

Annex B
Test method for air leakage past syringe piston during aspiration, and for separation of piston and plunger

B.l Principle

The syringe nozzle is connected to a reference female conical hub and the syringe partially filled with water. A negative pressure is applied through the nozzle, and the syringe inspected for leakage past the piston and seal(s) and to determine if the piston becomes detached from the plunger.

B.2 Apparatus and reagents

8.2.1 Reference steel female conical fitting, in accordance with IS0 594-1.

8.2.2 Support and device that clamps the syringe plunger, in a fixed position.

8.2.3 Equipment for producing, controlling and measuring vacuum, as shown in figure B.1, comprising a vacuum pump with air bleed control, a manometer and a vacuum-tight valve.

8.2.4 Freshly boiled water, cooled to a temperature of (20 +-5)C

6.3 Procedure

6.3.1 Draw into the syringe a volume of water (B.2.4) of not less than 25 % of the nominal capacity.

B.3.2 With the nozzle uppermost, withdraw the plunger axially until the fiducial line is at the nominal capacity graduation line and clamp (6.2.2) the plunger in this position as shown in figure B.1.

B.3.3 Connect the syringe nozzle to the reference steel female conical fitting (6.2.1).

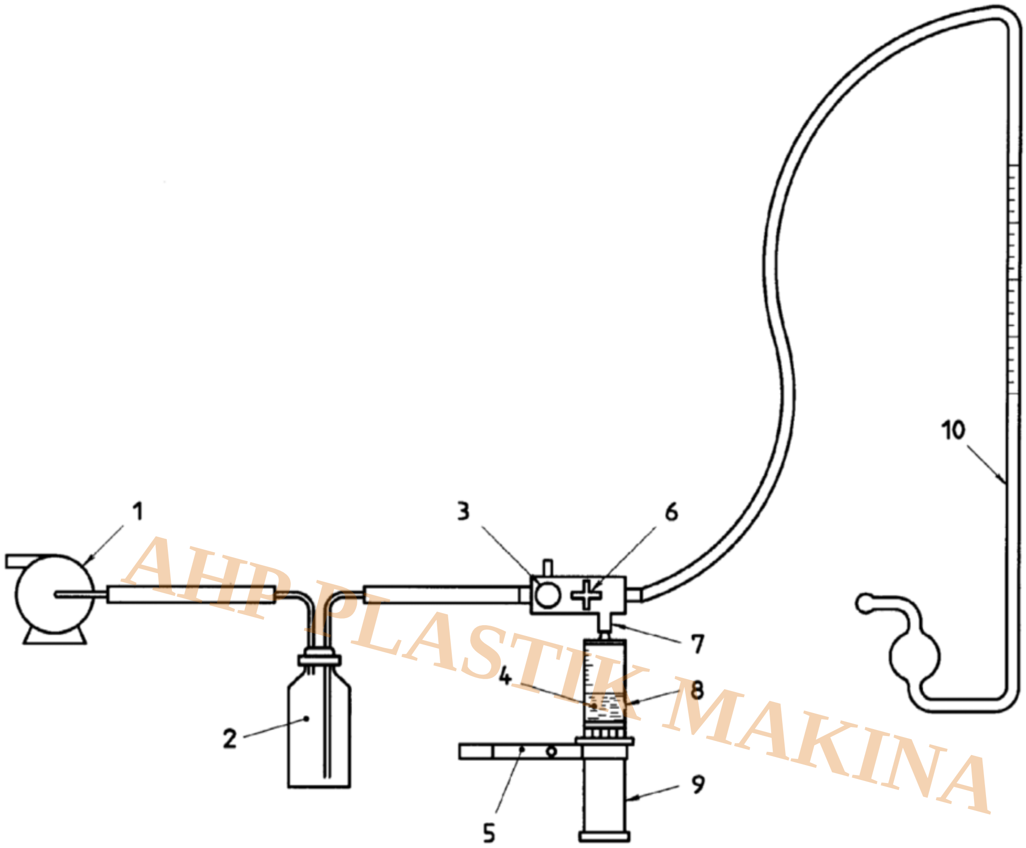
B.3.4 Arrange the test equipment (B.2.3) as shown in figureB.1. Switch on the vacuum pump with the air bleed control open.

6.3.5 Adjust the bleed control so that a gradual re duction in pressure is obtained and a manometer reading of 88 kPaâ€• below ambient atmospheric pressure is reached.

6.3.6 Examine the syringe for leakage of air past the piston or seab).

6.3.7 Isolate the syringe and manometer assembly by means of the vacuum-tight valve.
6.3.8 Observe the manometer reading for (60 +5)s and record any fall in the reading.

6.3.9 Examine the syringe to determine if the pis ton has become detached from the plunger.



1. Vacuum pump
2. Bottle trap
3. Fine bleed control
4. Nominal capacity graduation line
5. Clamp
6. Vacuum-tight valve
7. Female conical fitting complying with ISO 594-1
8. Water to not less than 25% of nominal capacity
9. Syringe
10. Manometer

Figure B.1 — Apparatus for aspiration test

Annex C
C.1 Principle

The syringe is weighed dry and after having been filled with, and emptied of, water. The dead space is inferred from the mass of the residual water.

C.2 Apparatus and reagents

C.2.1 Balance, capable of determining a difference in mass of 0,2 g or less to an accuracy of 7 mg.

C.2.2 Distilled or deionized water, of grade **3** in

accordance with IS0 3696.

C.3 Procedure

C.3.1 Weigh (C.2.1) the empty syringe.

C.3.2 Fill the syringe to the nominal capacity gradu ation line with water (C.2.21, taking care to expel all air bubbles and to ensure that the level of the meniscus of the water coincides with the end of the nozzle lumen.
C.3.3 Expel the water by fully depressing the plunger, and wipe dry the outer surfaces of the syringe.

C.3.4 Reweigh the syringe.

C.4 Calculation of results

Determine the mass, in grams, of water remaining in the syringe by subtracting the mass of the empty syringe from the mass of the syringe after expulsion of the water. Record this value as the dead space in millilitres, taking the density of water as 1 O00 kg/m3.

Annex D
Test method for liquid leakage at syringe piston under compression
D.l Principle

The syringe is filled with water, the syringe nozzle sealed, the plunger arranged in the most disadvanta geous orientation in relation to the barrel and a force applied in an attempt to induce leakage past the pis ton and seal(s).

D.2 Apparatus and reagents
D.2.1 Device for sealing or occluding the syringe nozzle
NOTE 6 This may comprise the reference steel female conical fitting in accordance with IS0 594-1, suitably sealed or occluded.
D.2.2 Device for applying slideways force to the **syringe plunger,** in the range 0,25 N to 3 N.
D.2.3 Device for applying an axial force to the barrel and/or plunger, to generate pressures of 200 kPa and **300** kpa
D.2.4 Water.

D.3 Procedure
D.3.1 Draw into the syringe a volume of water (D.2.4) exceeding the nominal capacity of the syringe.

D.3.2 Expel air and adjust the volume of water in the syringe to the nominal capacity.

0.3.3 Seal (D.2.1) the syringe nozzle.

D.3.4 Apply a sideways force (D.2.2) to the push- button at right angles to the plunger to swing the plunger radially about the piston seal(s) with a force as given in table 1.

Orientate the plunger to permit the maximum de flection from the axial position.

D.3.5 Apply an axial force (D.2.3) to the syringe so that the pressure given in table 1 is generated by the relative action of the piston and barrel, Maintain the pressure for (30 +5)s.
D.3.6 Examine the syringe for leakage of water past the piston seal(s).

Annex G
Test method for forces required to operate plunger

G. 1 Principle

A mechanical testing machine such as in figureG.l is used to move the syringe plunger and to aspirate and expel water, whilst the force exerted and the plunger travel are recorded.

G.2 Apparatus and reagents

G.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.

G.2.2 Reservoir, open to the atmosphere, and having tubing of inside diameter (2,7 +- 0,l) mm for connecting it to the syringe to be tested.

G.2.3 Water.

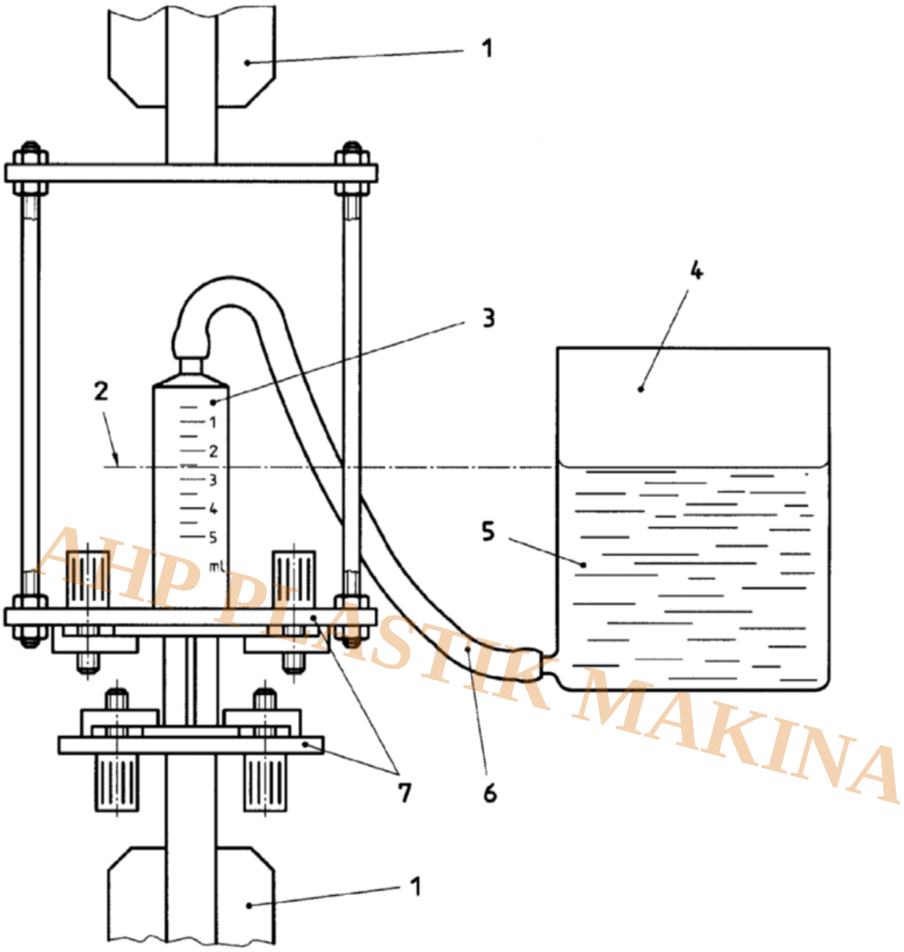
G.3 Procedure

G.3.1 Remove the syringe from the package and mount it in the testing machine (G.2.1) as shown in figureG.1. Move the syringe plunger once until the fiducial line reaches the total graduated capacity graduation line, and then return it so that the fiducial line reaches the zero graduation line.
G.3.2 Connect the nozzle of the syringe to the tubing of the reservoir (G.2.2) Add to the reservoir water (G.2.3) at (23 +- 2) *C* 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 (see figure G.1).

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

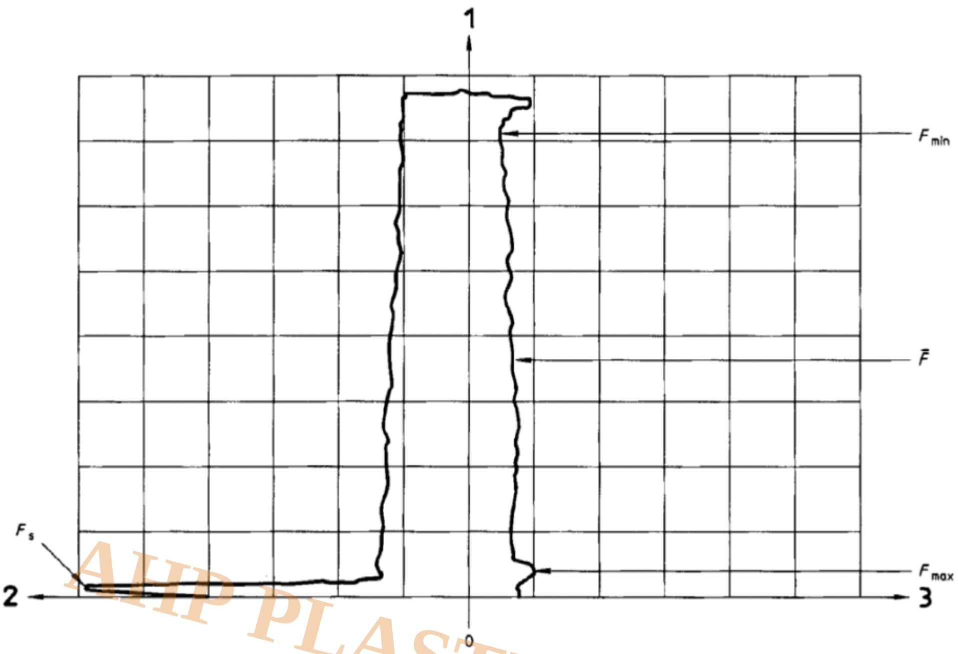
G.3.4 Start the testing machine so that it withdraws the syringe plunger, at a rate of (100 +- 5) mm/min, to the graduation line that indicates the nominal capacity, thereby drawing water from the reservoir to the syringe.
NOTE 9 The presence of air in the syringe nozzle will not affect the results of the test.

G.3.5 Withdraw the syringe plunger until the fiducial line has reached the nominal capacity graduation line. Stop the plunger travel and readjust the recorder to zero. Wait 30 s. Reverse the testing machine and re turn the plunger to its original position, thereby expelling the water from the syringe into the reservoir.



1. Jaw of mechanical testing machine (G.2.1)
2. Water level at approximately the mid-point of the syringe
3. Syringe being tested
4. Reservoir (G.2.2)
5. Water (G.2.3)
6. Connecting tubing (G.2.2)
7. Adjustable mounts to accommodate different nominal capacities of syringe

Figure G.1 — Apparatus for determining forces to operate plunger



1. Plunger travel
2. Force (newtons) during withdrawal of plunger
3. Force (newtons) during return of plunger

Figure G.2 — Examples of graph of forces required to operate plunger

6.4 Calculation of results

G.4.1 From the recording of plunger travel and force applied (see figure G.21, determine the following:

a)the force required ***(F,)*** to initiate movement of the plunger Â¡.e. the peak force recorded when the testing machine starts to withdraw the plunger (see G.3.4);

b)the mean force ***(F)*** during return of the plunger (Â¡.e. the estimated or integrated mean value while

the testing machine is returning the plunger (see G.3.5);
c)the maximum force **(Fmax)** during return of the plunger (see G.3.5);
d) the minimum force Pmin during return of the plunger (see G.3.5).
G.4.2 Proposed values for the forces required to operate the plunger are given in table G.1.

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

Nominal capacity of syringe, V ml	Initial force, F_s max. N	Mean force, $\bar{F}$ max. N	Maximum force, F_{max} N	Minimum force, F_{min} N
$V < 2$	10	5	$\ngtr$ (2,0 × measured $\bar{F}$) or (measured $\bar{F}$ + 1,5 N), whichever is the higher	$\nless$ (0,5 × measured $\bar{F}$) or (measured $\bar{F}$ − 1,5 N), whichever is the lower
$2 \leqslant V < 50$	25	10	$\ngtr$ (2,0 × measured $\bar{F}$) or (measured $\bar{F}$ + 1,5 N), whichever is the higher	$\nless$ (0,5 × measured $\bar{F}$) or (measured $\bar{F}$ − 1,5 N), whichever is the lower
$50 \leqslant V$	30	15	$\ngtr$ (2,0 × measured $\bar{F}$) or (measured $\bar{F}$ + 1,5 N), whichever is the higher	$\nless$ (0,5 × measured $\bar{F}$) or (measured $\bar{F}$ − 1,5 N), whichever is the lower

Category

1. Equipment for Standards
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