International Standard 595/1

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Reusable all-glass or metal-and-glass syringes for medical use — Part 1: Dimensions

Seringues réutilisables en verre ou en verre et métal à usage médical — Partie 1: Dimensions

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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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 595/1 was prepared by Technical Committee ISO/TC 84, *Syringes for medical use and needles for injections*.

Together with ISO 595/2 it cancels and replaces ISO Recommendation R 595-1967, of which it constitutes a technical revision.

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

Reusable all-glass or metal-and-glass syringes for medical use — Part 1: Dimensions

1 Scope and field of application

This part of ISO 595 specifies dimensions for reusable all-glass or metal-and-glass syringes for medical use, having a graduated capacity from 1 to 100 ml. It also specifies requirements for the graduated capacity of syringes.

ISO 595/2 specifies the design, the performance requirements and the corresponding test methods for reusable syringes.

NOTE — The term "all-glass syringe" relates to syringes with a barrel and piston made entirely of glass, with either a glass or a metal nozzle. The term "metal-and-glass syringe" relates to syringes with a glass barrel, a metal nozzle and a piston which may be either metal or partially metal.

2 References

ISO 594, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment —*

Part 1: General requirements.

Part 2: Lock fittings. [1]

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

3 Range of sizes

Syringes shall be designated by their graduated capacity in millilitres. The range of sizes of syringes shall be in accordance with table 1.

4 Capacity of syringes

4.1 Determination of capacity

The capacity corresponding to any scale interval shall be defined by the volume of water at 20 °C expelled from the syringe when the fiducial line of the piston traverses that interval. The capacity can be conveniently determined by weighing the expelled fluid.

4.2 Tolerance on the graduated capacity and other capacities

The tolerance limits on the graduated capacity and on any capacity greater than half the graduated capacity shall be in accordance with table 1. The tolerance limits on any capacity less than half the graduated capacity shall be ± 5 % of that capacity or the smallest scale interval, whichever is the greater.

5 Dimensions

5.1 Syringes

The dimensions of all-glass and metal-and-glass syringes shall be as designated in figure 1 and as given in tables 2 and 3.

The dimensions of all-glass syringes shall be as given in table 4 and those of metal-and-glass syringes as given in table 5.

5.2 Barrel

The barrel shall be of such a length that the syringe has a usable capacity of at least 10 % greater than its nominal capacity.

5.3 Bore of nozzle

The dimensions of the bore of the nozzle shall be as given in table 4 for all-glass syringes and as given in table 5 for metal-and-glass syringes.

6 Graduated scale

6.1 Scale

The scale shall be graduated at intervals in accordance with table 1 and as illustrated in figure 2.

1) At present at the stage of draft. (Revision, in part, of ISO/R 594-1967.)

The graduation lines shall be clearly defined, legible, durable and of uniform thickness. They shall lie in planes essentially at right angles to the longitudinal axis of the barrel.

The graduation lines shall be evenly spaced along the longitudinal axis between the zero line and the line for the graduated capacity.

When the syringe is held vertically with the conical tip uppermost and with the scale to the front, either the ends of all the graduation lines to the left of the scale shall lie vertically beneath each other, or the graduation lines shall be bisected by a line parallel to the longitudinal axis of the barrel.

The lengths of the long graduation lines shall be greater than or equal to the values given in table 1, and the short graduation lines shall be approximately equal to half the length of the long lines.

6.2 Numbering of scale

The graduation lines shall be numbered in accordance with figure 2. The figures shall be clearly defined, durable and easily legible.

When the syringe is held vertically with the conical tip uppermost and with the scale to the front, the figures shall appear on the right of the scale if the left ends of the graduation lines lie vertically beneath each other; if the graduation lines are bisected by a line parallel to the longitudinal axis of the barrel, the figures shall appear either above or below the lines when the syringe is held horizontally. The figures shall be in a position such that they will be bisected by a prolongation of the graduation line to which they relate.

The figures shall be close to, but shall not touch, the ends of the graduation lines to which they relate.

6.3 Minimum length of scale

The minimum length of scale shall be in accordance with table 1.

6.4 Position of scale

When the piston is fully inserted into the syringe, i.e. as near to the nozzle end of the barrel as possible, the zero graduation mark of the scale shall coincide with the fiducial line on the piston.

7 Fiducial line of piston

The end of the piston which enters the barrel of the syringe shall have a clearly defined line to serve as a fiducial line for taking scale readings and for setting the piston on any graduation line.

If, however, the end of the piston is bevelled, the edge of the bevel in contact with the barrel of the syringe shall constitute the fiducial line.

8 Nozzle

The male conical fitting of the syringe nozzle shall comply with the requirements laid down in ISO 594/1 and/or ISO 594/2.

9 Packaging

Each syringe shall be packed and boxed with cushioning material to ensure protection of the contents against breakage during normal handling, transit and storage.

10 Marking

10.1 On the barrel and the plunger

The barrel shall be legibly and indelibly marked with the following information:

a) the capacity, in millilitres;

b) the manufacturer's or supplier's name or registered mark;

c) the identification number or symbol of the barrel and the plunger, if necessary to denote matching parts.

10.2 On the unit container

The unit container shall be marked with the following information:

a) a description of contents, to include nominal capacity and type, for example 5 ml all-glass syringe;

b) the name and address of the manufacturer or distributor.

Table 1 — Syringes, range of sizes, graduated scales and tolerances on graduated capacities

Graduated capacity of syringe	Minimum length of scale *B*	Scale interval	Minimum length of long graduation marks	Tolerances on the graduated capacity and on any capacity greater than half the graduated capacity
ml	mm	ml	mm	%
1 (short)	22	0,1	5	± 5
1 (long)	49	0,01 or 0,05	2,5	± 5
2	23	0,1 0,2 or 0,5	6 8	± 5
5	35	0,2 or 0,5	8	± 4
10	45	1	10	± 4
20	50	1 or 2	13	± 4
30	63	1 or 2	13	± 4
50	71	5	16	± 4
100	93	5	20	± 4

Table 2 — Designation of dimensions of all-glass syringes

Dimension		Description
Principal	*B*	Minimum length of the scale
	C	Minimum distance from the graduation mark corresponding to graduated capacity to the flanged end of the barrel of the syringe
	E	Minimum distance from the flange (including thickness) to the end of the piston
	L	Maximum total length of the syringe
Secondary	*H*	Bore of nozzle

Table 3 — Designation of dimensions of metal-and-glass syringes

Dimension		Description
Principal	*B*	Minimum length of the scale
	F	Minimum distance from the graduation mark corresponding to graduated capacity to the end of the metal cap
	G	Minimum distance from the end of the metal cap to the end of the piston
	L	Maximum total length of the syringe
Secondary	*H*	Bore of nozzle

Table 4 — Dimensions of all-glass syringes

Dimensions in millimetres

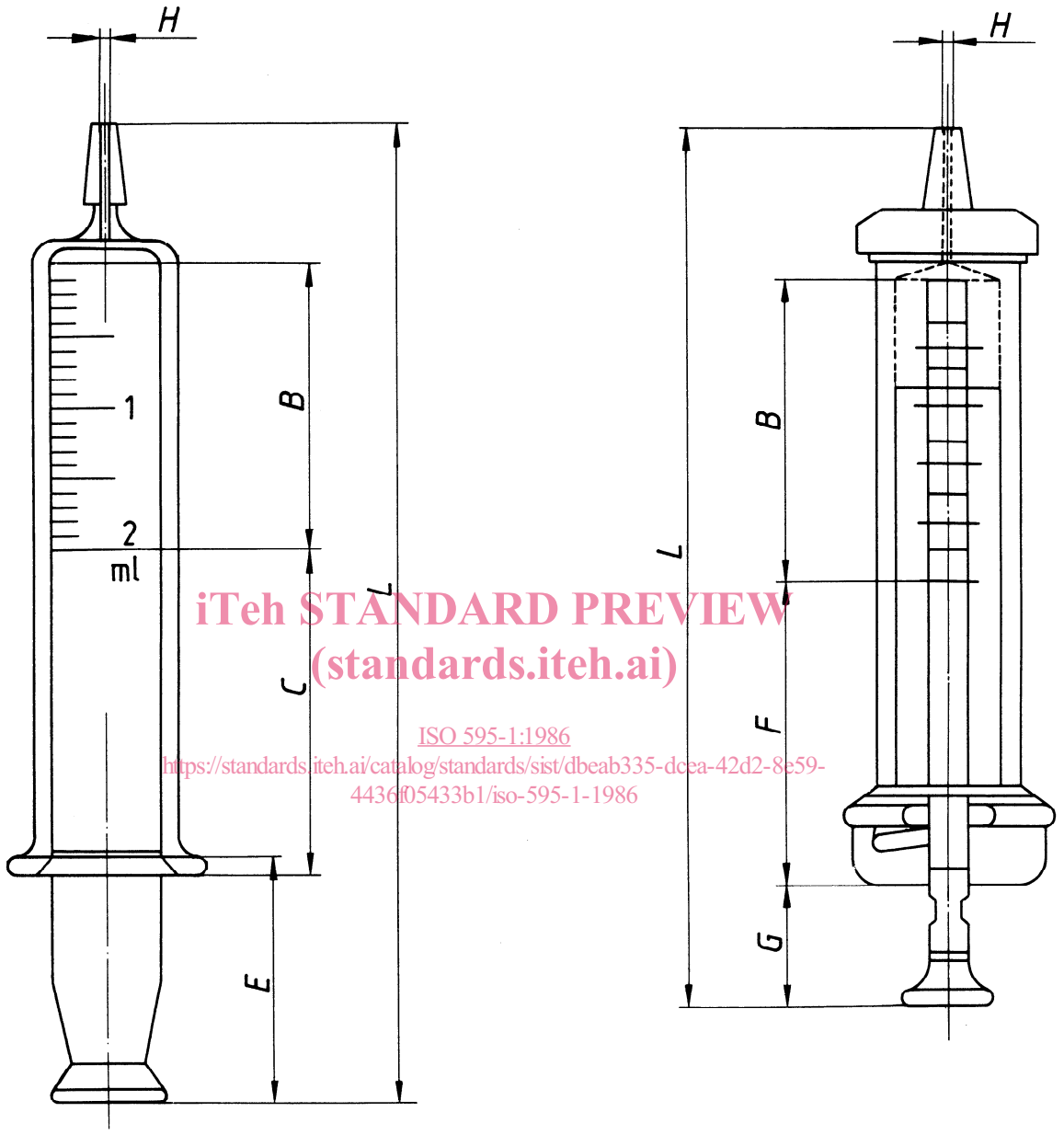
Graduated capacity of syringe ml	*C*	*E*	*L*	*H*
1 (short)	25	10	95	0,7 to 1,8
1 (long)	25	10	110	0,7 to 1,8
2	25	10	100	0,7 to 1,8
5	25	13	125	0,7 to 1,8
10	30	15	140	1,0 to 2,1
20	30	15	165	1,0 to 2,1
30	35	15	180	1,0 to 2,1
50	40	20	205	1,0 to 2,1
100	40	20	245	1,0 to 2,2

Table 5 — Dimensions of metal-and-glass syringes

Dimensions in millimetres

Graduated capacity of syringe ml	*F*	*G*	*L*	*H*
1	20	7,5	95	1,0 to 1,8
2	20	7,5	100	1,0 to 1,8
5	22	12,5	125	1,0 to 1,8
10	28	12,5	140	1,5 to 2,1
20	28	12,5	165	1,5 to 2,1
30	30	12,5	180	1,5 to 2,1
50	35	12,5	205	1,5 to 2,1
100	35	12,5	245	1,5 to 2,1

NOTE — The method used to determine dimensions *F* and *G* of metal-and-glass syringes [see figure 1b)] differs from that used to determine dimensions *C* and *E* of glass syringes, since the thickness of the metal cap of metal-and-glass syringes is variable and is not specified in this part of ISO 595. The purpose of dimensions *E* and *G* is to ensure that there is sufficient space around the piston head to facilitate manipulation.



a) All-glass syringe

b) Metal-and-glass syringe

NOTE — The illustrations are given solely for the purpose of representing the dimensions specified. The indications of shape do not form a part of the requirements laid down in this part of ISO 595.

Figure 1 — Designation of dimensions of hypodermic syringes

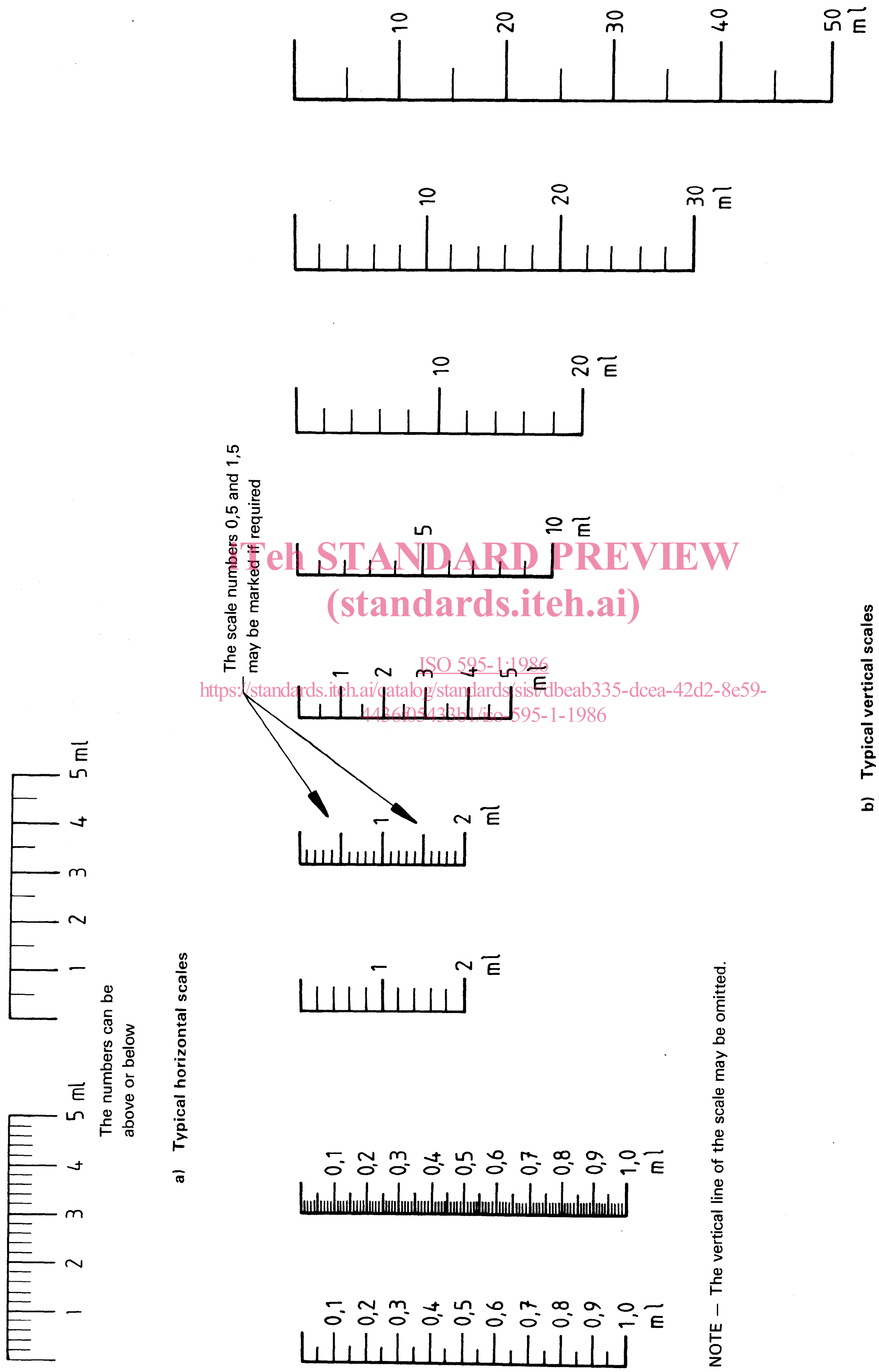


Figure 2 — Scale graduations of reusable syringes for medical use