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R 595

SYRINGES FOR MEDICAL USE

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BRIEF HISTORY

The ISO Recommendation R 595, *Syringes for Medical Use*, was drawn up by Technical Committee ISO/TC 84, *Syringes for Medical Use and Needles for Injections*, the Secretariat of which is held by the Association Française de Normalisation (AFNOR).

Work on this question by the Technical Committee began in 1957 and led, in 1963, to the adoption of a Draft ISO Recommendation.

In September 1964, this Draft ISO Recommendation (No. 740) was circulated to all the ISO Member Bodies for enquiry. It was approved, subject to a few modifications of an editorial nature, by the following Member Bodies:

Argentina	Greece	Republic of South Africa
Bulgaria	Hungary	Spain
Canada	Ireland	Sweden
Chile	Israel	Switzerland
Czechoslovakia	Korea, Rep. of	Turkey
Denmark	Netherlands	U.A.R.
France	New Zealand	Yugoslavia
Germany	Poland	

One Member Body opposed the approval of the Draft:

United Kingdom.

The Draft ISO Recommendation was then submitted by correspondence to the ISO Council, which decided, in July 1967, to accept it as an ISO RECOMMENDATION.

ISO Recommendation R 595 July 1967

SYRINGES FOR MEDICAL USE

INTRODUCTION

This ISO Recommendation relates to syringes for general use in medicine and specifies essential requirements for capacity, graduation and basic dimensions.

Requirements for certain performance characteristics, notably for a test for leakage past the piston, have been deferred in order to effect early issue of this ISO Recommendation.

1. SCOPE

This ISO Recommendation specifies requirements for all-glass and metal-and-glass syringes of graduated capacity from 1 ml up to 100 ml for general use.

It does not cover insulin syringes and syringes made of plastics materials although certain requirements will apply equally to syringes of these types.

NOTES

1. The term *all-glass syringe* relates to syringes with a barrel and piston made entirely of glass, with the nozzle either of glass or of metal, or of any other material. 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. ISO Recommendation R 596, *Hypodermic Needles*, deals with hypodermic needles suitable for use with syringes complying with the requirements of this ISO Recommendation.

2. DETERMINATION OF CAPACITY

The capacity corresponding to any scale interval is determined by the volume of water at 20 °C expelled from the syringe when the fiducial line of the piston traverses that interval.

3. TOLERANCES ON THE GRADUATED CAPACITY

The admissible tolerances on the graduated capacity are given in Table 1, page 8.

4. RANGE OF SIZES

Syringes should be designated by their graduated capacity. The range of sizes of syringes should be as given in Table 1, page 8.

5. DIMENSIONS

The dimensions of all-glass syringes are given in Table 2, page 9. The dimensions of metal-and-glass syringes are given in Table 3, page 9.

The dimensional characteristics of all-glass and metal-and-glass syringes are given in Figure 1, page 11.

6. GRADUATION

6.1 Length of scale

The length of the scale should be as given in Table 1.

6.2 Position of scale

When the piston is fully inserted into the syringe, the centre of the zero graduation line of the scale should be within $\pm$ 0.2 mm of the fiducial line on the piston.

6.3 Graduation lines

The scale should be graduated in accordance with Table 1, page 8, and Figure 2, page 12.

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

There should be no evident irregularity in the spacing of the graduation lines and they should be evenly spaced 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, the ends of all the graduation lines to the left of the scale should lie vertically beneath each other.

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

6.4 Numbering of graduation lines

The graduation lines should be numbered in accordance with Figure 2. The figures should 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 should appear on the right of the scale and in a position such that they would be bisected by a prolongation of the graduation line to which they relate.

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

7. FIDUCIAL LINE OF PISTON

The end of the piston which enters the barrel of the syringe should 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 may constitute the fiducial line.

8. NOZZLE

The nozzle on the end of the syringe should comply with the requirements of ISO Recommendation R 594, *Conical Fittings for Syringes, Needles and other Medical Equipment—Definition and Dimensional Characteristics for Conical Fittings with a 6% and a 10% Taper* and should be capable of fitting the conical socket of hypodermic needles which comply with the requirements of ISO Recommendation R 596, *Hypodermic Needles*.

9. THERMAL RESISTANCE

9.1 Resistance to thermal shock

The components of the dismantled syringe at a temperature of 20 °C (obtained by immersion in water at this temperature) should be plunged into boiling water for not less than 30 seconds, following which the components should be removed and rapidly immersed in water at 20 °C.

After this treatment, the components, including graduation lines and other marks, should not reveal any deterioration.

9.2 Resistance to dry heat

The syringes assembled, in the case of all-glass syringes, or dismantled in the case of metal-and-glass syringes, should be first maintained at a temperature of 20 °C, and then subjected to dry heat in an air oven at $180 \begin{smallmatrix} +10 \\ -0 \end{smallmatrix}$ °C for 30 minutes.

After this treatment, the components, including graduation and other marks, should not reveal any deterioration.

10. MARKING

The syringe should be legibly and durably marked as follows:

— indication of the unit of capacity: ml (millilitres)

— if required, a means of identifying the barrel and its corresponding piston.

TABLE 1

Range of sizes, graduated scales and tolerances on graduated capacities of syringes

Graduated capacity of syringe ml	Length of scale (dimension *B*) mm	Scale interval ml	Minimum length of long graduation marks mm	Tolerances on the graduated capacity and on any capacity greater than half the graduated capacity %
1	25 ± 3	0.1	5	± 5
2	31 ± 4	0.1	6	± 5
5	41 ± 5	0.5	8	± 4
10	52 ± 6	1	10	± 4
20	58 ± 6	2	13	± 4
50	88 ± 10	5	16	± 4
100	105 ± 10	5	20	± 4

TABLE 2

Dimensions of all-glass syringes

Graduated capacity of syringe ml	Length of the non-graduated part of the barrel of the syringe (dimension *C*)		Minimum length of projection of piston (dimension *E*) mm	Total maximum length (dimension *L*) mm
	minimum mm	maximum mm		
1	25	35	10	95
2	25	35	10	100
5	25	35	13	125
10	30	40	15	140
20	30	40	15	165
50	40	50	20	205
100	40	60	20	245

TABLE 3

Dimensions of metal-and-glass syringes

Graduated capacity of syringe ml	Minimum length of the non-graduated part of the barrel of the syringe (dimension *F*) mm	Minimum length of projection of piston (dimension *G*) mm	Total maximum length (dimension *L*) mm
1	20	12.5	95
2	20	12.5	100
5	22	12.5	125
10	28	12.5	140
20	28	12.5	165
50	35	12.5	205
100	35	12.5	245

NOTE.—The method used to determine dimensions *F* and *G* of metal-and-glass syringes (see Fig. 1 *b*) 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 ISO Recommendation. The purpose of dimensions *E* and *G* is to ensure that there is sufficient space around the piston head to facilitate manipulation.