

ISO

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION

ISO RECOMMENDATION R 596

HYPODERMIC NEEDLES

1st EDITION

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BRIEF HISTORY

The ISO Recommendation R 596, *Hypodermic Needles*, 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. 741) 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
Bulgaria	Hungary	South Africa
Canada	Ireland	Spain
Chile	Israel	Sweden
Czechoslovakia	Korea, Rep. of	Switzerland
Denmark	Netherlands	Turkey
France	New Zealand	U.A.R.
Germany	Poland	Yugoslavia

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.

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HYPODERMIC NEEDLES

INTRODUCTION

This ISO Recommendation relates to hypodermic needles with the purpose of specifying their essential requirements and notably the dimensional characteristics, the designation, and the marking of hubs and of packages.

Requirements for the quality of needles in relation to materials used, the mechanical properties of the tube, the shape of the needle point, and to the factors relating to sharpness, and to other tests have been deferred in order not to delay publication of this ISO Recommendation and will be studied later.

1. SCOPE

This ISO Recommendation specifies the requirements of hypodermic needles, 0.5 to 2 mm in diameter, for general medical use.

It covers needles for giving injections (subcutaneous, intramuscular, intravenous, etc.) and for aspirating.

It does not deal with needles for *single use*.

NOTE.—ISO Recommendation R 595, *Syringes for Medical Use*, covers syringes suitable for use with hypodermic needles complying with the requirements of this ISO Recommendation.

2. DEFINITIONS

2.1 Length of needle. The exposed length of the needle as measured from the tip of the point to the joint with the hub (see Fig. 1).

2.2 Point of needle (or bevel). The bevelled portion of the end of the needle.

2.3 **Angle of point.** The angle between the bevel and the longitudinal axis of the needle (see Fig. 1, angle α).

2.4 **Hub (or mount).** The component carrying the needle tube having a conical socket to fit the nozzle of the syringe.

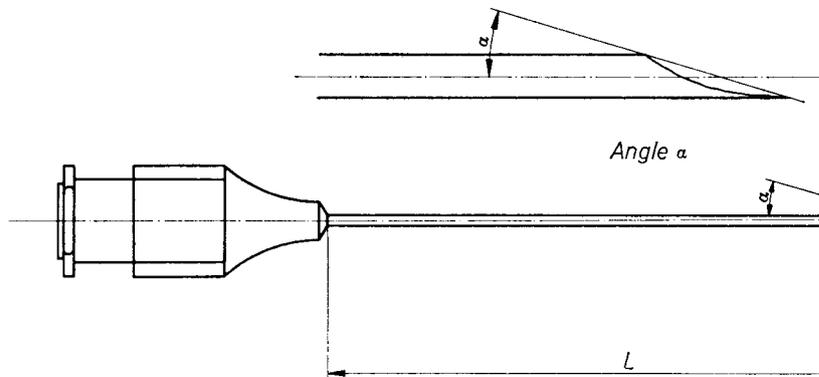


FIG. 1. — Dimensions of hypodermic needles

3. SIZES OF NEEDLES

The designations and the dimensions of hypodermic needles are given in Table 1.

The nominal diameter of the needles is designated by a *round* number closely corresponding to the basic diameter expressed in tenths of millimetres.

TABLE 1

Designations and dimensions of hypodermic needles

Nominal diameter (in tenths of millimetres)			5	6	8	10	12	16	20
Actual external diameter D mm			0.50 ± 0.04	0.63 ± 0.04	0.80 ± 0.04	1.00 ± 0.04	1.25 ± 0.06	1.60 ± 0.06	2.00 ± 0.06
Nominal length		Actual length L mm							
mm	in								
12	$\frac{1}{2}$	12.5 ± 1.0	+						
16	$\frac{5}{8}$	16.0 ± 1.0	+	+					
20	$\frac{3}{4}$	20.0 ± 1.0	+	+	+				
25	1	25.0 ± 1.0	+	+	+				
30	$1 \frac{1}{4}$	31.5 ± 1.5		+	+	+			
40	$1 \frac{1}{2}$	40.0 ± 1.5		+	+	+	+	+	+
50	2	50.0 ± 1.5		+	+	+	+	+	+
60	$2 \frac{1}{2}$	63.0 ± 1.5		+	+	+	+	+	+

NOTE.—The diameters and lengths of the needles given in Table 1 are based on the R 10 series of preferred numbers in accordance with ISO Recommendation R 3, *Preferred Numbers—Series of Preferred Numbers*. This series of preferred numbers may, if required, be used for other sizes outside the range of sizes given in this ISO Recommendation.