INTERNATIONAL

RECOMMENDATION

OIML R 26

Edition 1978 (E)

Medical syringes

Seringues médicales

OIML R 26 Edition 1978 (E)

ORGANISATION INTERNATIONALE
DE MÉTROLOGIE LÉGALE

INTERNATIONAL ORGANIZATION
OF LEGAL METROLOGY

Foreword

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This publication – reference OIML R 26 (E), edition 1978 – which is now under the responsibility of OIML TC 18/SC 5 *Measuring instruments for medical laboratories*, was sanctionned by the International Conference of Legal Metrology in 1972.

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MEDICAL SYRINGES

with glass barrels

Where subjected to compulsory verification, medical syringes with glass barrels must conform to the following specification:

1 SCOPE

1.1 This Recommendation applies to medical syringes with glass barrels, intended for general use.

1.2 The Recommendation does not concern syringes for insulin, syringes for tuberculin or syringes with barrels of a substance other than glass, eg of plastic.

2 CAPACITY AND CALIBRATION

2.1 The total nominal capacity must be:
0.5-1 - 2 - 5 - 10 - 20 - 50 - 100 - 200 cubic centimetres or millilitres.

2.2 The syringes must be constructed either with or without a scale.

2.3 The syringes must be calibrated at a temperature of + 20°C.

2.4 The total nominal capacity and the capacity between any two scale marks are defined by the volume of water at + 20°C delivered by the syringe when the fiducial edge on the piston traverses the whole of the scale or the relevant part of it.

3 MATERIALS

3.1 As far as their physical and chemical properties are concerned, the materials used for medical syringes must be suitable for the purpose for which they are to be used.

The materials used and the processing of them must be such as to allow of the syringes being cleaned and sterilized.

In normal conditions of use there must be adequate security against leakage, against variations in total nominal capacity and partial capacities and against deterioration of the scale and the inscriptions on the syringes.

3.2.1 The barrels of the syringes must be of glass.

3.2.2 The glass must be for practical purposes free of internal stresses; it must have a resistance to water corresponding to at least the third hydrolytic class (Mylius's method).

3.2.3 The materials used for the piston and the barrel fittings (metal, glass, ceramic) must have a thermal expansion approximately equal to that of the glass used in the barrel, so that the syringes will satisfy the conditions laid down at 4.2.1 and 4.3.1, even at a temperature of + 40°C.

3.2.4 Materials other than glass must be at least as resistant as nickel to air and to the liquids normally used.

3.2.5 Syringes in which the pistons and barrel fittings are of materials other than glass, metal or ceramic require special approval.

3.3 For joining parts which are not detachable, only irreversible lutings or metal welds must be used.

If compressible packings are used in order to prevent leakage, their compressibility must have no effect on the total nominal capacity.

3.4 Syringes must stand up to the treatment detailed below without, in general, suffering any damage and, in particular, without the welds or lutings developing leaks or showing visible deterioration:

a) for all syringes: an abrupt temperature change of 80 °C, the initial temperature being + 20°C (by immersion in boiling water)

b) for ordinary syringes: a temperature of + 120 °C in water vapour/steam, (the duration of exposure to this temperature being one hour).

c) for syringes marked with the temperature for their sterilization: the temperature marked, in dry air, (the duration of exposure to this temperature being one hour).

4 CONSTRUCTION

4.1 Syringes must consist of:

the barrel, the piston,

the tip for fitting the needle;

if necessary, they may be equipped with special additional fittings (in particular for connecting the tip to the barrel).

4.2.1 In all possible positions of the fiducial edge on the piston along the scale of the syringe, the fit of the piston in the barrel must be such that the quantity of distilled water leaking in the course of half a minute between the barrel and the piston does not exceed a value corresponding to the maximum permissible error in tests on the total nominal capacity, under a hydrostatic pressure of 3 bars in the case of syringes of a total nominal capacity of up to 10 cm^3, and 2 bars in the case of syringes of a total nominal capacity of 20 cm^3 or over.

4.2.2 The joints of the fittings and of tip with the barrel must be such that, on testing at the pressure described in paragraph 4.2.1, no more than traces of moisture appear.

4.2.3 The conical tip for fitting the needle must be constructed in such a way as to ensure a tight fit with all needles having cones of the following dimensions:

	Conical fitting with 6% taper	Conical fitting with 10% taper
Diameter of the aperture of the cone	from 4.270 mm to 4.315 mm	from 3.300 mm to 3.380 mm
Minimum length of the cone	7.500 mm	7.400 mm

4.3.1 Readings showing the position of the piston in the barrel, relative to the scale marks, shall be taken, as appropriate, by means of any index which enables readings to be taken easily, for example:

- the circular edge, very sharp and clearly visible, of the junction between the head of the piston and the cylindrical body of the piston,

- the circular edge, in contact with the barrel, of the bevel at the end of the piston (in the case of pistons with bevelled ends),

- the plane surface of the head of the piston (in the case of glass pistons),

- the edge of a plate or marker of coloured glass fused* on to the head of the piston.

The thickness of the plate or of the index used for** taking readings must not be greater than the length, measured on the barrel, corresponding to one half of the maximum permissible error on verification of the total nominal capacity.

4.3.2 The edge of the piston head, the edge of the bevel, the piston head, the edge of the plate, or any other index used in positioning the piston must coincide with the zero mark when the piston is fully inserted. Any discrepancy must not exceed one quarter of the scale spacing (the smallest division), nor 0.5 mm.

4.4.1 For syringes with rod-type pistons and caps (eg glass and metal syringes) when the piston is fully withdrawn the barrel must contain above the reference mark indicating the total nominal capacity a free space which, for syringes with a scale graduated in 0.01 or 0.02 cm^3 must be at least one tenth of the total nominal capacity, and for other syringes of a total nominal capacity of:

0.5 cm^3	at least	0.1 cm^3
1	''	''	0.2 ''
2	''	''	0.3 ''
5	''	''	0.6 ''
10	''	''	1.0 ''
20	''	''	2.0 ''
50	''	''	4.5 ''
100	''	''	7.0 ''
200	''	''	12.0 ''

4.4.2 In the case of other types of syringe (eg syringes with glass pistons), the length of the part of the barrel not marked with a scale must be, in the case of syringes of a total nominal capacity of:

0.5 cm^3	at least	20 mm
1	''	''	25 ''
2	''	''	25 ''
5	''	''	25 ''
10	''	''	30 ''
20	''	''	30 ''
50	''	''	40 ''
100	''	''	40 ''
200	''	''	55 ''

Translator's notes:

* The word "collée" has been omitted from the French but in the translation it is assumed that it was meant to be included.

** The French 'ou' should be 'au' to make sense.

5 SCALE

5.1.1 Only scales with the following scale intervals are permitted:

Nominal capacity	**Scale intervals**													
cm^3	0.01	0.02	0.05	0.1	0.2	0.5	1	2	5	10	20	50	100	**cm^3**
0.5	+	+	+	+										
1	+	+	+	+	+	+								
2		+	+	+	+	+	+							
5				+	+	+	+							
10					+	+	+	+	+					
20						+	+	+	+	+				
50							+	+	+	+				
100								+	+	+	+	+		
200										+	+	+	+	

5.1.2 The scale spacing (distance between two consecutive scale marks on the barrel) and the distance corresponding to the maximum permissible error on verification of the total nominal capacity must be at least:

0.8 mm in the case of syringes graduated in 0.01 or 0.02 cm^3,
1.0 mm in the case of other syringes.

5.2.1 The scale must be regular and uniform*.

The difference in length of neighbouring scale divisions must not exceed one tenth of the length of a scale division.

5.2.2 The reference marks indicating the total nominal capacity and the scale marks must be made on the barrel.

5.2.3 The zero mark must be visible, though part of its thickness may be covered by the tip or its mounting.

5.2.4 In the case of scales graduated in:

0.01	0.1	1	10 cm^3	every fifth mark	)	must be longer
0.02	0.2	2	20 cm^3	every fifth mark	)	than the other
0.05	0.5	5	50 cm^3	every alternate mark	)	un-numbered marks

5.2.5 The length of the numbered marks must be at least four tenths of the diameter of the barrel, and the length of the other marks at least two tenths of the barrel diameter, but not less than 2 mm.

5.2.6 The marks must lie in planes at right angles to the axis of the barrel.

The thickness of the marks may be up to two tenths of the length of a scale division, but may not be more than 0.4 mm nor less than 0.25 mm.

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* Division of equal length and value
Scale marks of constant thickness

The thickness must be the same for all the marks and must remain constant throughout the length of a mark (it is not permissible to give prominence to certain marks by making them thicker).

The nature and execution of the marks must not be such as to give rise to appreciable errors in relation to the maximum permissible error on verification.

5.3.1 The numbers must be unambiguous and easily legible.

5.3.2 In the case of scales graduated in:

0.01	0.1	1	10 cm^3	every fifth or every tenth mark must be numbered,
0.02	0.2	2	20 cm^3	every fifth or every tenth mark must be numbered,
0.05	0.5	5	50 cm^3	every alternate mark, every fourth mark or every tenth mark must be numbered.

5.4 The scale marks and the numbers, inscriptions or signs must be indelible.

Scale marks and numbers, inscriptions or signs which are etched or applied while the material is hot must be filled with indelible colouring matter insoluble in boiling water (whether pure or containing soda), showing no deterioration when the syringe is exposed to steam at + 120°C for one hour, and resistant to pure alcohol and methylated spirit.

In the case of syringes which are marked with a temperature the colouring matter must remain unaffected when the syringe is exposed for one hour in dry air to the temperature marked.

6 INSCRIPTIONS

6.1 The total nominal capacity must be indicated in cubic centimetres by the symbol "cm^3" or in millilitres by the symbol "ml".

6.2 The barrels of syringes with easily detachable fittings and tips (eg with screw connections) must bear a type designation or a manufacturer's mark.

7 MAXIMUM PERMISSIBLE ERRORS

7.1 Maximum permissible errors on verification:

a) the maximum permissible errors for the total nominal capacity or for all capacities equal to or greater than half the total nominal capacity shall be:

– for syringes of a total nominal capacity of up to 2 cm^3 ± 5 % of the capacity measured,

– for syringes of a total nominal capacity of over 2 cm^3 ± 4 % of the capacity measured,

b) the maximum permissible errors (absolute errors) for capacities of less than half the total nominal capacity shall be equal to half the maximum permissible error for the total nominal capacity,

c) nevertheless, in both cases a and b above the absolute value of those errors must not exceed the scale interval.

7.2 Maximum permissible errors in use.

The maximum permissible errors in use shall be identical with the maximum permissible errors on verification.

8 STAMPING

8.1 The verification mark must be made on the barrel, along the generatrix opposite to the graduation.

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