

Reusable hypodermic syringes for insulin injection —

**Part 2: Specification for syringes for use
with insulin of strength 100 units
per millilitre**

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Committee (HCC/-) to Technical Committee HCC/2, upon which the following bodies were represented:

- Association of Clinical Pathologists
- British Diabetic Association
- British Surgical Trades Association Incorporated
- Department of Health and Social Security
- Disposable Hypodermic and Allied Equipment Manufacturers' Association
- Glass Manufacturers' Federation
- Medical Sterile Products Association
- Pharmaceutical Society of Great Britain
- Coopted members

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Foreword

This first revision of BS 1619-2 has been prepared under the direction of the Health Care Standards Committee, and supersedes BS 1619-2:1982 which is withdrawn.

BS 1619-2:1982 was prepared with the approval of the British Diabetic Association to take into account the availability of insulin of strength 100 units per millilitre (U-100 insulin), and gave requirements for syringes of 0.5 mL and 1 mL total graduated capacity, graduated in a manner specific to the use of U-100 insulin. It was expected that glass and metal would continue to be employed extensively in the manufacture of insulin syringes; however, provision was made for the use of other materials of equal or superior performance.

This revision introduces a new method for measuring the length of the graduation lines, together with revised tolerances on the line length. It also introduces revised requirements for the piston brake of the syringe.

BS 1619-1 (declared obsolescent in 1986) deals with syringes intended for use with insulin of strength 20, 40 and 80 units per millilitre.

Attention is drawn to the work on the standardization of conical fittings (6 % taper) presently under consideration by Technical Committee ISO/TC 84, Syringes for medical use and needles for injections, of the International Organization for Standardization (ISO), of which the UK is an active member. ISO 594-1, giving requirements for the Luer taper, has been implemented as an identical British Standard BS 3930-1 and it is expected that ISO 594-2 giving requirements for the Luer lock fitting will, when published, be similarly adopted as BS 3930-2.

Certification requirement. Attention is drawn to the fact that products conforming to this British Standard must be certified by the British Standards Institution for the purposes of the Drug Tariff, Department of Health and Social Security and Welsh office (1984), the Drug Tariff of the Health and Personal Social Services of Northern Ireland (1981) and the Drug Tariff, Scottish Home and Health Department (1984). (Details of the certification scheme are given on the inside back cover.)

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 8, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

1 Scope

This Part of BS 1619 specifies requirements for hypodermic syringes for the injection of insulin of strength 100 units per millilitre (U-100 insulin) and which are suitable for use with hypodermic needles as specified in BS 3522 and BS 5081-2, and with those having a 6 % (Luer) conical taper as specified in BS 3930-1 and BS 3930-2.

Syringes are specified in the following sizes:

- a) 0.5 mL total graduated capacity, graduated into 50 scale intervals of 1 unit of U-100 insulin (equivalent to 0.01 mL);
- b) 1.0 mL total graduated capacity, graduated into 50 scale intervals of 2 units of U-100 insulin (equivalent to 0.02 mL).

This Part of BS 1619 does not apply to syringes intended for single use, to syringes intended for use with strengths of insulin of other than 100 units per millilitre, or to syringes having special features, e.g. pre-setting or click-stop mechanisms, intended for use by blind or partially sighted persons.

NOTE The titles of the publications referred to in this standard are listed on page 8.

2 Definition

For the purposes of this Part of BS 1619 the following definition applies.

graduated capacity

that volume of water at 20 ± 5 °C expelled from the syringe when the fiducial line on the piston traverses a given scale interval or intervals

NOTE Figure 1 gives nomenclature used to describe the parts of a syringe.

3 Materials

The materials used in the construction of the syringe shall be such as to enable the syringe to comply with the requirements of clauses 10 and 11. The piston and the barrel shall be free from striae and similar visible defects that distort the graduations and affect the visibility of the fiducial line or edge.

NOTE Guidance for the selection of materials is given in Appendix A.

4 Sizes of syringe

4.1 The total graduated capacity of syringes for the injection of U-100 insulin shall be either 0.5 mL or 1.0 mL.

4.2 The tolerances on the total graduated capacity shall be ± 0.01 mL for syringes of 0.5 mL capacity, and ± 0.02 mL for syringes of 1 mL capacity.

5 Overall dimensions of syringe

The overall dimensions of the syringe shall be as shown in Figure 1.

NOTE See Appendix B for recommendations for carrying cases for syringes of the dimensions shown in Figure 1.

6 Graduated scale

6.1 Graduation lines

The graduation lines shall be clear, legible and durable lines of uniform thickness, evenly spaced, and they shall lie in planes at right angles to the axis of the barrel.

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 shall lie vertically beneath each other.

The lengths of the arcs subtended by the graduation lines shall be as shown in Figure 2, and the minimum difference between lines of different lengths shall be 0.75 mm.

NOTE 1 The tolerances on line length shown in Figure 2 will result in at least 0.75 mm difference except in the case of the medium and long lines of the 0.5 mL syringe. In this case, the actual length of one or both lines should be such as to maintain the required differential.

NOTE 2 The left hand ends of the graduation lines may optionally be joined by a line parallel to the longitudinal axis of the barrel (see Figure 2).

6.2 Overall length of scale

The minimum overall length of the scale shall be as given in Table 1.

6.3 Position of scale

When the piston is fully inserted, that is as near to the nozzle end of the barrel as it will go, the zero graduation line of the scale shall coincide with the fiducial line or edge on the piston (see 8.3).

6.4 Scale intervals

The scale shall be graduated at intervals as given in Table 1 and as shown in Figure 2.

6.5 Numbering of scale lines

The graduation lines to be numbered shall be as shown in Figure 2. The scale numbers shall be bold, durable and legible.

When the syringe is held vertically with the conical tip uppermost and with the scale to the front, the numbers shall appear upright on the right of the scale and in a position such that they would be bisected by a prolongation of the graduation mark to which they relate.

The numbers shall be next to, but shall not touch, the ends of the graduation marks to which they relate.