INTERNATIONAL STANDARD

ISO 11499

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Dental cartridges for local anaesthetics

Cartouches à usage dentaire pour anesthésiques locaux

Reference number
ISO 11499:1997(E)

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. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 11499 was prepared by Technical Committee ISO/TC 106, *Dentistry,* Subcommittee SC 4, *Dental instruments.*

Annex A of this International Standard is for information only.

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Introduction

The safe and efficient operation of dental cartridges for local anaesthetics depends on their freedom from leakage, the control of the forces required to initiate and maintain the plunger movement, and the absence of large air bubbles.

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this International Standard, but it is recommended that in assessing possible biological hazards, reference be made to ISO 10993-1 and ISO 7405.

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Dental cartridges for local anaesthetics

1 Scope

This International Standard gives specific performance requirements for single-use dental cartridges for local anaesthetics of 1,8 ml and 2,2 ml nominal capacity.

It specifies tests for leakage, plunger movement, extractable volume and underfilling, and lists essential overall dimensions to ensure that the cartridge will fit dental cartridge syringes complying with ISO 9997.

Labelling requirements are also specified.

NOTE — A list of International Standards for certain types of cartridge component is given in annex A.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards listed below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 9997:1990, *Dental cartridge syringes.*

ISO 7885:1996, *Sterile, single-use dental injection needles.*

3 Requirements

3.1 Freedom from leakage of anaesthetic solution

The filled cartridge shall be free from leakage of anaesthetic solution at the plunger and disc. Tests shall be carried out in accordance with 4.2 and 4.3.

3.2 Force required for plunger movement

3.2.1 The force F_1 to initiate movement of the plunger shall not exceed 30 N.

3.2.2 The force F_2 to sustain movement of the plunger throughout its effective length shall not exceed 20 N and shall not be less than 2 N.

Tests shall be carried out in accordance with 4.4.

3.3 Underfilling of cartridges

The air bubble shall not be visible below the rim of the aluminium cap.

Tests shall be carried out in accordance with 4.1 and 4.5.1.

3.4 Biocompatibility

Components of the cartridge in contact with the anaesthetic solution shall not release any substances which may adversely affect the therapeutic effectiveness of the injectable products, including those substances which may exhibit toxic, pyrogenic or haemolytic reactions. See introduction for application of other International Standards.

NOTE — Since biological tests are usually required by most of the national Pharmacopoeia or related regulations of health authorities, they are mandatory for producers and users in countries where they exist.

3.5 Extractable volume

When tested, the extractable volume shall not be less than the capacity stated in 5.1 a) and 5.2 b).

Tests shall be carried out in accordance with 4.1 and 4.6.

3.6 External dimensions of the assembled cartridge

3.6.1 Overall length

1,8 ml cartridge: max. 64,6 mm.

2,2 ml cartridge: max. 77,5 mm.

3.6.2 Overall diameter (including label if fitted)

The maximum overall diameter shall be 9,0 mm.

4 Test methods

4.1 Test conditions

Conduct all tests at (23 ± 2) °C.

4.2 Visual inspection

Carry out visual inspection at normal visual acuity without magnification.

4.3 Test for leakage of local anaesthetic solution

4.3.1 Apparatus

4.3.1.1 Test rig, to support the cartridge. A suitable rig is shown in figure 1.

4.3.2 Procedure

Support the cartridge to be tested in the test rig.

Apply a test force of 60 N axially to a free-fitting round rod which is in contact with the cartridge plunger.

Maintain the force for 1 min and inspect the cartridge for leaks during this period.

4.4 Determination of force needed for plunger movement

4.4.1 Apparatus

4.4.1.1 Machine, capable of moving the plunger rod of the syringe at a constant velocity of (50 ± 1) mm/min. See annex A.

4.4.1.2 Syringe holder, capable of mounting a dental cartridge syringe, for example as shown in figure 2.

4.4.1.3 Sterile single-use dental injection needle, 0,4 mm × 35 mm complying with ISO 7885.

4.4.1.4 Dental cartridge syringe, complying with ISO 9997.

4.4.2 Procedure

Place the cartridge to be tested in the syringe and attach the needle. Mount the loaded syringe into the syringe holder. Operate the testing machine at the rate of 50 mm/min and record the force, F_1, required to initiate movement of the plunger and the force F_2, required to sustain movement of the plunger throughout the effective length.

4.5 Size of air bubble

Hold the cartridge vertically with the cap uppermost and tap it on a horizontal surface to dislodge any air bubbles adhering to the side walls. Observe from a horizontal angle whether the air bubble is visible below the rim of the cap.

4.6 Extractable volume

4.6.1 Apparatus

4.6.1.1 Dental cartridge syringe, in accordance with ISO 9997.

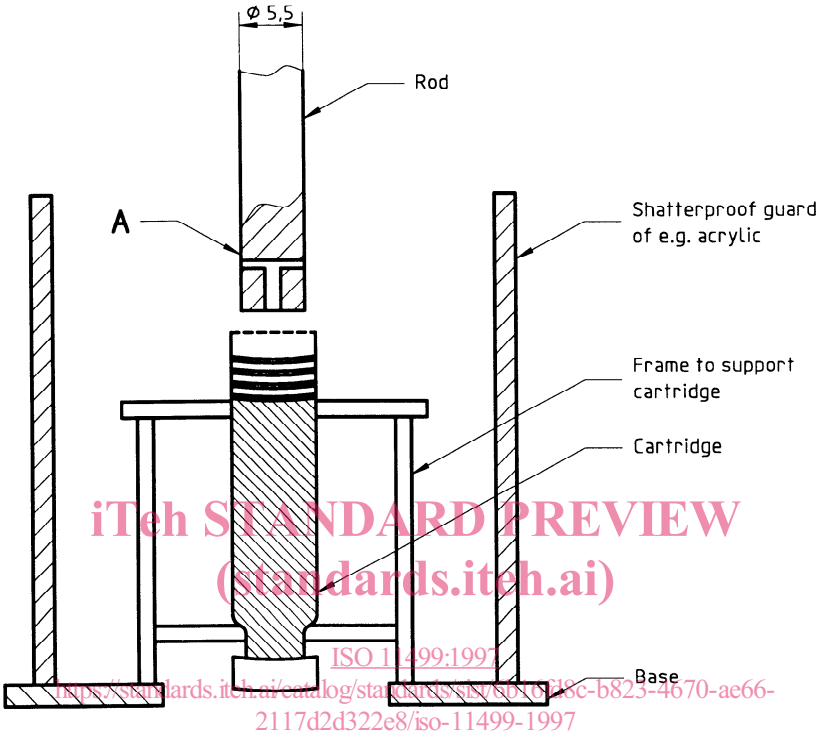
4.6.1.2 Sterile, single-use dental injection needle of diameter 0,4 mm, in accordance with ISO 7885.

4.6.1.3 Suitable container, graduated in millilitres.

4.6.2 Procedure

Load the cartridge to be tested into the dental cartridge syringe (4.6.1.1) and screw the needle (4.6.1.2) in position. Slowly empty the cartridge into the container (4.6.1.3) and measure the volume of anaesthetic solution extracted.

Dimension in millimetres



A: Cross-holes to allow escape of fluid when testing cartridges fitted with diaphragm-type plungers

Figure 1 — Apparatus for testing dental cartridges for leakage of local anaesthetic solution

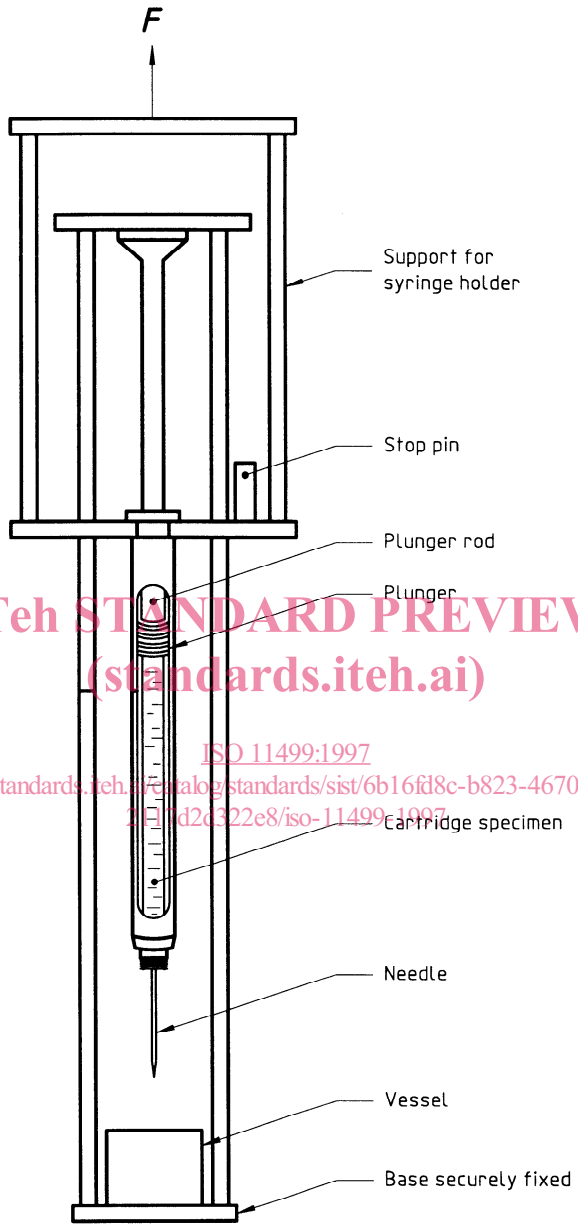


Figure 2 — Apparatus for determining force required for dental cartridge plunger movement