INTERNATIONAL STANDARD

ISO 8536-5

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Infusion equipment for medical use —

Part 5:
Burette type infusion sets

Matériel de perfusion à usage médical —

Partie 5: Appareils de perfusion type burette

Reference number
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Contents

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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 8536-5 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical use*.

ISO 8536 consists of the following parts, under the general title *Infusion equipment for medical use*:

— *Part 1: Infusion glass bottles*

— *Part 2: Closures for infusion bottles*

— *Part 3: Aluminium caps for infusion bottles*

— *Part 4: Infusion sets for single use*

— *Part 5: Burette type infusion sets*

— *Part 6: Freeze drying closures for infusion bottles*

— *Part 7: Infusion caps made of aluminium-plastics combinations*

Introduction

Infusion sets for the administration of infusion fluids (electrolytes, carbohydrates, amino acids, fat emulsions) for medical therapy, as described in ISO 8536:4, are routinely used in combination with large volume parenteral solution containers, e.g. glass bottles and plastics bags. Their design allows adjustment of the flow rate, with only rough estimate of volume, usually stated in drops per millilitre infused. Glass bottles and plastics containers graduations have only wide-spaced intervals and are fairly inaccurate and insufficient when a dosage and readings of only millilitres are considered.

The burette type infusion sets, which are referred to in this part of ISO 8536 as burette sets, are intended for paediatric use or for other purposes for which the quantity of fluid administered needs to be carefully monitored or controlled.

Infusion equipment for medical use —

Part 5:
Burette type infusion sets

1 Scope

This part of ISO 8536 specifies requirements for types of single-use burette type infusion sets (hereinafter "burette sets") of 50 ml, 100 ml and 150 ml nominal capacity for medical use in order to ensure compatibility of use with containers for infusion solutions and intravenous equipment.

The materials and components of the sets are validated by various test methods (type tests) and, in addition, tests are performed for the release of lots of finished sets (lot tests).

This part of ISO 8536 specifies requirements applicable to sterilized burette sets intended for single use.

Secondary aims of this part of ISO 8536 are to provide

a) specifications relating to the quality and performance of materials used in infusion sets;

b) a unified presentation of terms and designations for infusion sets.

In some countries, the national pharmacopoeia or other national regulations are legally binding and take precedence over this part of ISO 8536.

2 Normative reference

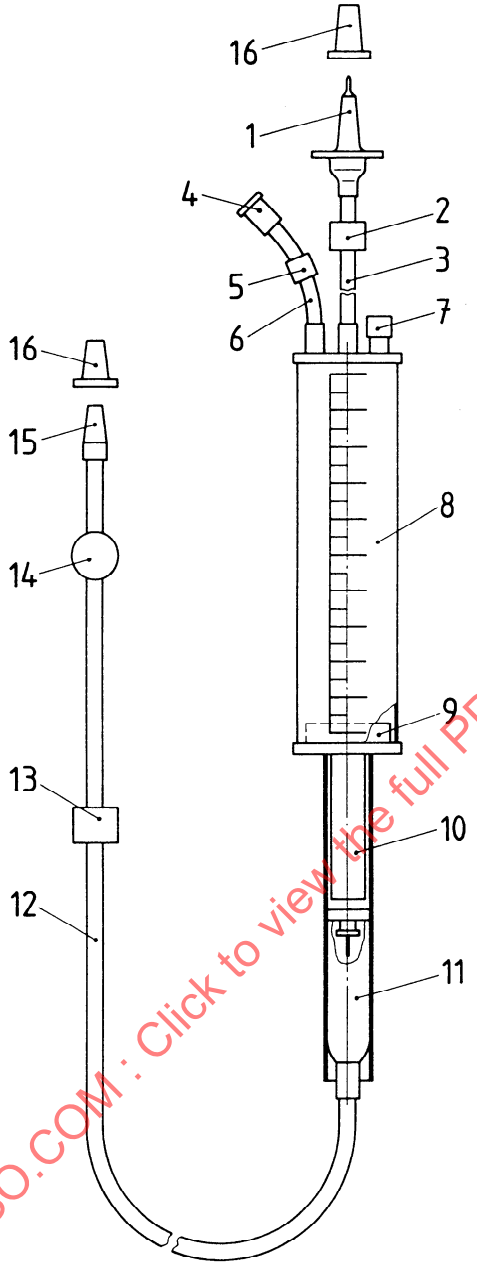
The following standard contains provisions which, through reference in this text, constitute provisions of this part of ISO 8536. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this part of ISO 8536 are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8536-4:1987, *Infusion equipment for medical use — Part 4: Infusion sets for single use.*

3 General requirements

3.1 Components

A typical burette set is illustrated in figure 1. The following components are specified in ISO 8536-4: closure-piercing device, tubing, air filter, air inlet, injection site, fluid filter, drip-chamber, flow regulator, male fitting, protective caps.



1	Closure-piercing device	9	Shut-off valve
2	Clamp	10	Fluid filter
3	Tubing	11	Drip chamber
4	Air filter	12	Tubing
5	Air filter shut-off device	13	Flow regulator
6	Air inlet	14	Injection site
7	Injection site	15	Male fitting
8	Graduated burette	16	Protective cap

Figure 1 — Example of typical burette set

3.2 Sterilization

The burette set shall be sterilized by a validated sterilization process in its unit container.

3.3 Maintenance of sterility

The burette set shall be provided with protective caps which maintain sterility of the internal parts until the set is used.

3.4 Designation example

The code designation of a burette type (BT) infusion set (IS) of nominal capacity 100 ml which complies with this part of ISO 8536 is as follows:

Burette Type ISO 8536 - BT - IS - 100

4 Materials

The manufacturer shall undertake appropriate tests to demonstrate compliance with the requirements laid down in ISO 8536:4 and in this part of ISO 8536.

5 Physical requirements

Physical requirements for burette sets shall be in accordance with ISO 8536:4. In addition, the burette set shall comply with the requirements in 5.1 to 5.3.

5.1 Design

5.1.1 The burette shall consist of a transparent, substantially colourless tube of rigid or semi-rigid plastics material.

5.1.2 The burette shall be provided with filtered air-venting capability located in a position above the top graduation mark.

5.1.3 The burette shall be capable of receiving fluid from the main container and of being closed off and serving as a separate self-vented reservoir.

5.2 Size of burette

The nominal size of the burette shall be designated by the total graduated capacity.

5.3 Graduated scale

5.3.1 The burette scale shall be graduated at intervals as given in table 1.

Table 1 — Size and scale intervals for burettes

Nominal capacity of burette ml	Scale intervals max. ml	Numbered scale intervals max. ml	Tolerance on any graduated capacity exceeding half nominal capacity %
≤ 50	1	5	± 4
> 50	5	10	

5.3.2 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 burette.

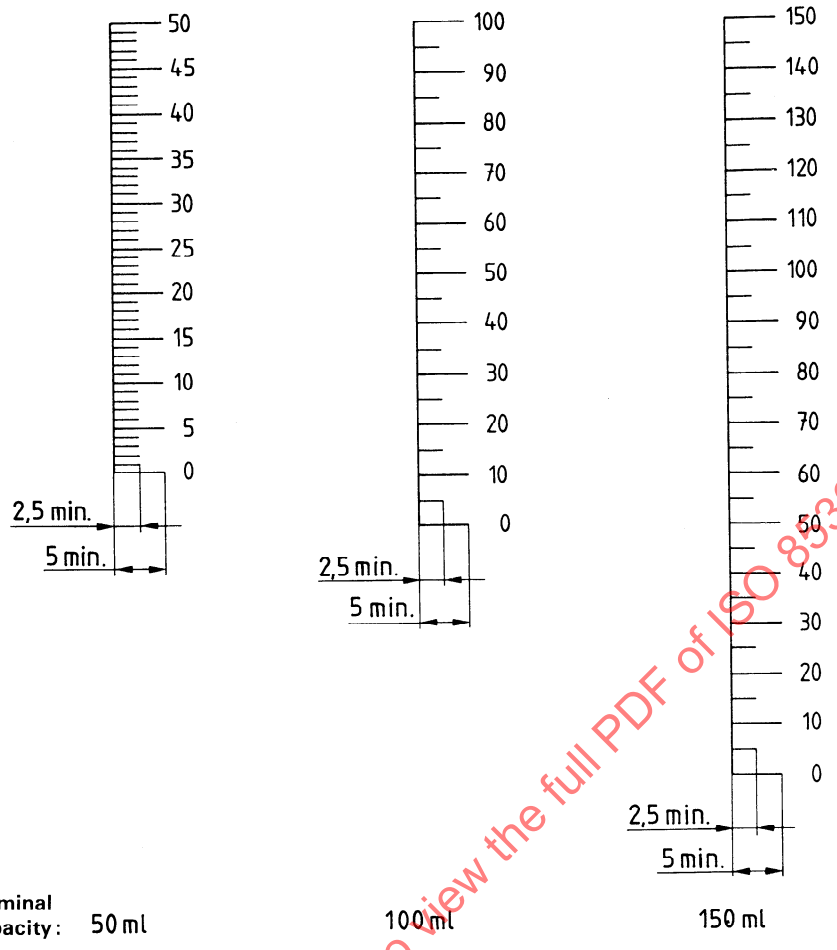
5.3.3 When the burette is held vertically, with the closure-piercing device uppermost and with the scale to the front, one end of any graduation line shall lie vertically below the corresponding end of the graduation line above and vertically above the corresponding end of the graduation line below.

The ends may optionally be joined by a line parallel to the longitudinal axis of the burette (see figure 2).

5.3.4 The lengths of the graduation lines shall be as given in figure 2.

5.3.5 The graduation lines to be numbered shall be as illustrated in figure 2. The scale numbers shall be bold, durable and legible, and shall be close to, but not touching, the ends of the graduation lines to which they relate.

5.3.6 The zero position mark on the chamber shall be located in a position which compensates for the volume displaced by any shut-off device, the position of outlet relative to the bottom of the burette or any other feature of the bottom cap which may affect the reading.



NOTE — The vertical lines are optional.

Figure 2 — Typical graduated scales for use in burette sets

5.4 Drip chamber

The drip chamber shall be sufficiently flexible to assist the procedure of priming, and to permit continuous observation of the fall of drops. The liquid shall enter the drip chamber through a tube which projects into the chamber. The distance between the end of the drip tube and the filter shall be not less than 40 mm. The wall of the drip chamber shall not be closer than 5 mm to the end of the drip tube. The drip tube shall be such that 20 or 60 drops of distilled water at 20 °C and at a flow rate of 50 drops/min ± 5 drops/min deliver 1 ml ± 0,1 ml (1 g ± 0,1 g).

5.5 Flow rate

Burette sets with a 60 drop per ml drop-former shall deliver not less than 1 000 ml of a sodium chloride solution [ρ(NaCl) = 9 g/l] at 23 °C ± 2 °C in 40 min under a static head of 1 m.

6 Chemical requirements

These requirements shall be in accordance with ISO 8536-4.

7 Biological requirements

These requirements shall be in accordance with ISO 8536-4.

8 Marking and labelling

8.1 Unit container

The unit container of each burette set shall display the following minimum information in a legible form:

a) a description of the contents in words and/or diagram;

b) the word "STERILE" in prominent lettering;

c) indications that the burette set is free from pyrogens and for single-use only;

d) instructions for the use of the burette set, including a warning note about checking that seals are intact and about detached protective caps;

e) Warning note: "Not for blood and cellular components";

f) the nominal dimension of an intravenous needle, if included;

g) the year and month of sterilization, where applicable, and the date of expiry, where applicable;

h) the batch designation;

i) the manufacturer's name and address and/or the name and address of the supplier;

j) a statement that 20 or 60 drops of distilled water delivered by the drip tube are equivalent to 1 ml $\pm$ 0,1 ml (1 g $\pm$ 0,1 g);

k) a statement to the effect that the burette set shall be destroyed after use.

Additional information may be provided.

8.2 Shelf or multi-unit container

Shelf or multi-unit containers shall display the following minimum information in a legible form:

a) a description of contents and diagram;

b) the quantity of burette sets;

c) the word "STERILE" in prominent lettering and indications that the burette set is free from pyrogens and for single-use only;

d) the name of the manufacturer or supplier;

e) the batch designation;

f) the year and month of sterilization, where applicable and the date of expiry, where applicable;

g) the recommended storage conditions, if any.

Additional information may be provided.

8.3 Outer or transit container

Outer or transit containers shall display the following minimum information in a legible form:

a) the name and address of the manufacturer or supplier;

b) a description of contents;

c) the quantity of burette sets;

d) the batch designation;

e) the year and month of sterilization, where applicable and the date of expiry, where applicable;

f) the recommended storage conditions, if any.

9 Packaging

9.1 The burette set shall be individually packed so that the set remains sterile during storage.

The unit container shall be sealed in such a manner that it cannot be opened and reclosed without clearly revealing that it has been opened.

If, in special cases, only the interior of the burette set is required to be sterile, a statement to this effect should be clearly marked on the shelf or multi-unit container.

9.2 The burette set shall be packed and sterilized in such a way that there are no flattened portions or kinks when the device is ready for use.