INTERNATIONAL STANDARD

ISO 8536-5

Second edition
2004-02-01

Infusion equipment for medical use —

Part 5: Burette infusion sets for single use, gravity feed

Matériel de perfusion à usage médical —

Partie 5: Appareils non réutilisables de perfusion à burette, à alimentation par gravité

Reference number
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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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

This second edition cancels and replaces the first edition (ISO 8536-5:1992), which has been technically revised.

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, gravity feed*

— *Part 5: Burette infusion sets for single use, gravity feed*

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

— *Part 7: Caps made of aluminium-plastics combinations for infusion bottles*

— *Part 8: Infusion sets for use with pressure infusion equipment*

— *Part 9: Fluid lines for use with pressure infusion equipment*

— *Part 10: Accessories for fluid lines for use with pressure infusion equipment*

— *Part 11: Infusion filters for use with pressure infusion equipment*

Infusion equipment for medical use —

Part 5: Burette infusion sets for single use, gravity feed

1 Scope

This part of ISO 8536 specifies requirements for types of single-use, gravity feed burette infusion 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.

This part of ISO 8536 also provides guidance on specifications relating to the quality and performance of materials used in infusion sets.

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

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

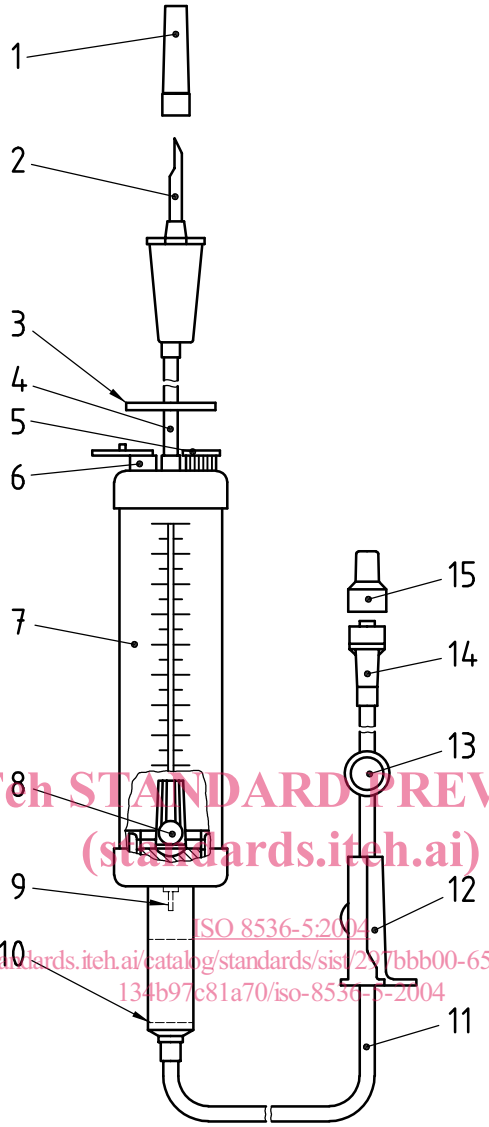
3 General requirements

3.1 The nomenclature to be used for components of burette infusion sets is given in Figure 1.

Figure 1 illustrate examples of the configuration of burette infusion sets; other configurations may be used provided they lead to the same results.

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

3.3 If a separate air-inlet device is used, it shall comply with ISO 8536-4.



Key

1 protective cap of the closure-piercing device
2 closure-piercing device [a]
3 ON/OFF clamp
4 tubing
5 injection site [b]
6 air inlet with air filter and closure
7 graduated burette
8 shut-off valve
9 drip tube
10 fluid filter [c]
11 tubing
12 flow regulator
13 injection site [b]
14 male conical fitting
15 protective cap of the conical fitting

[a] Air inlet with air filter is optional; if an air filter exists, a closure is optional.

[b] Injection site is optional.

[c] The fluid filter may be positioned at other sites, for example preferably near the patient access. Generally a fluid filter has a nominal pore size of 15 µm.

Figure 1 — Example of a burette set

4 Designation

The designation of a burette infusion set (BS), gravity feed (G), which complies with this part of ISO 8536 shall include the indication of burette set, a reference to this part of ISO 8536, the nominal capacity in millilitres (e.g. 100 ml) and the indication of gravity feed, as follows:

Burette set ISO 8536-5 — BS — 100 — G

5 Materials

The materials from which the burette infusion set and its components as given in Clause 3 are manufactured shall comply with the requirements in Clause 6. Where components of the burette infusion set come into contact with solutions, the materials additionally shall comply with the requirements specified in Clauses 7 and 8.

6 Physical requirements

6.1 General

Physical requirements for burette infusion sets shall be in accordance with ISO 8536-4 so far as applicable. In addition, the burette set shall comply with the requirements in 6.2 to 6.4.

6.2 Design

6.2.1 The burette shall consist of a tube of rigid or semi-rigid plastics material and shall permit observation of fluid in the chamber.

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

6.2.3 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.

6.3 Volume of burette

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

6.4 Graduated scale

6.4.1 The burette scale shall be graduated at intervals as given in Table 1.

Table 1 — Volume and scale intervals for burettes

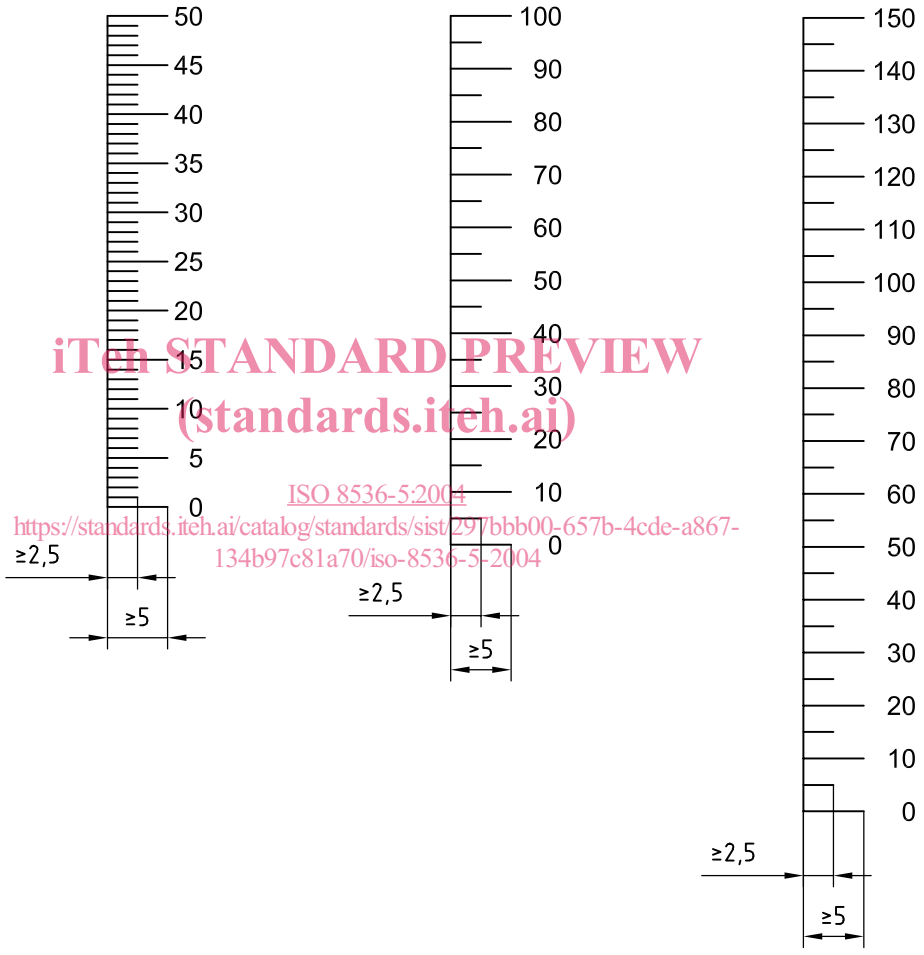
Nominal volume of burette ml	Scale intervals max. ml	Numbered scale intervals max. ml	Tolerance on any graduated capacity exceeding half nominal volume %
50	1	5	± 4
> 50	5	10	

6.4.2 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.

6.4.3 The lengths of the graduation lines shall be given in Figure 2. The ends may optionally be joined by a line parallel to the longitudinal axis of the burette (see Figure 2).

6.4.4 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.

6.4.5 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 can affect the reading.



Nominal volume:	**50 ml**	**100 ml**	**150 ml**

NOTE The vertical lines are optional.

Figure 2 — Typical graduated scales for use in burette sets

7 Chemical requirements

The requirements of ISO 8536-4 shall apply.

8 Biological requirements

The requirements of ISO 8536-4 shall apply.

9 Labelling

The requirements of ISO 8536-4 shall apply.

10 Packaging

The requirements of ISO 8536-4 shall apply.