International Standard

ISO 8536-5

Third edition
2026-11

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

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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This third edition cancels and replaces the second edition (ISO 8536-5:2004), which has been technically revised.

The main changes are as follows:

— a change of scope to consider burettes as components of infusion sets;

— a scope expansion to include additional applications of burettes in transfusion applications;

— addition or revision of clauses concerning light-resistance, the graduated scale, particulate contamination, air-inlet, leakage, and drop former requirements;

— removal of clauses concerning labelling, packaging, and disposal;

— addition of Annexes A, B, and C.

A list of all parts in the ISO 8536 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Infusion equipment for medical use —

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

1 Scope

This document specifies requirements for single-use burettes to be used as subcomponents within sterilised infusion and transfusion sets for single use under gravity feed conditions or with pressure infusion apparatus.

NOTE 1 Annex B provides explanations about the history of the development of the standard and summarises the different arguments discussed within ISO/TC 76 during the collaboration of this document.

NOTE 2 Annex C provides recommendations regarding sustainability.

NOTE 3 Annex D provides information on attributive and variable testing.

2 Normative references

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The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

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ISO 1135-4, *Transfusion equipment for medical use — Part 4: Transfusion sets for single use, gravity feed*

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

ISO 8536-8, *Infusion equipment for medical use — Part 8: Infusion sets for single use with pressure infusion apparatus*

ISO 8536-10, *Infusion equipment for medical use — Part 10: Accessories for fluid lines for single use with pressure infusion equipment*

ISO 8536-15, *Infusion equipment for medical use — Part 15: Light-protective infusion sets for single use*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 24072, *Aerosol bacterial retention test method for air-inlet filter on administration devices*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

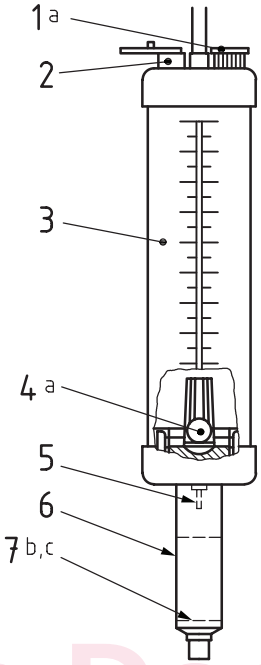
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4 General requirements

4.1 Design

4.1.1 A typical design along with the nomenclature to be used for burettes is given in Figure 1.



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Key

1	injection site
2	air inlet with air filter and closure
3	graduated burette
4	shut-off valve
5	drip tube
6	drip chamber
7	fluid filter/filter for blood and blood components
a	Optional.
b	See ISO 8536-4 for fluid filter requirements.
c	See ISO 1135-4 for blood filter requirements.

Figure 1 — Example of a burette

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

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

4.1.4 The burette shall be capable of receiving fluid from the main container (or from the injection site/Luer activated valve (LAV) as applicable) and of being closed off and serving as a separate self-vented reservoir.

4.1.5 For burettes that claim light protection, the requirements for drip chambers specified in ISO 8536-15 shall apply to the graduated burette and attached drip chamber which is denoted as items 3 and 6 in Figure 1.

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

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4.2 Graduated scale

4.2.1 The burette shall have either only one scale or more than one identical scale, which shall be graduated and numbered at least at the intervals given in Table 1. The unit of volume shall be marked on the burette.

NOTE The scale interval can be less (finer) than the scale interval given in Table 1.

4.2.2 Graduation lines shall be of uniform thickness. They shall lie in planes at right angles to the axis of the burette.

4.2.3 Graduation lines shall be evenly spaced along the longitudinal axis between the zero graduation line and the line for the total graduated capacity.

4.2.4 When the burette is held vertically, the ends of all graduation lines of similar length shall be vertically beneath each other.

The lengths of the short graduation lines on each scale are recommended to be approximately half the length of the long lines. If different graduation line configurations are used, this shall be submitted to usability evaluation in accordance with IEC 62366-1.

Examples of scales and the numbering of graduation lines are shown in Figure 2.

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

4.2.6 The accuracy of the scale shall be tested in accordance with Annex A and shall meet the accuracy requirements of Table 1.

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Table 1 — Volume and scale intervals for burettes

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Nominal capacity of burette	Tolerance on any graduated capacity			Minimum overall length of scale to nominal capacity mark	Scale interval	Increment between graduation lines to be numbered
	Less than 20 % nominal capacity	Less than half and more than or equal to 20 % nominal capacity	Equal to or greater than half nominal capacity			
V ml				mm	ml	ml
$V < 50$	±(1,5 % of V +1 % of expelled volume)		±5 % of expelled volume	67	2,0	10
$V \geq 50$	±(1,5 % of V +1 % of expelled volume)		±5 % of expelled volume	75	5,0	10

NOTE Expelled volume means all the liquid ejected to the point where the meniscus of the water level is coincident with the zero mark of the scale.

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