INTERNATIONAL STANDARD

ISO 8536-8

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Infusion equipment for medical use —

Part 8: Infusion equipment for use with pressure infusion apparatus

Matériel de perfusion à usage médical —

Partie 8: Matériel de perfusion pour utilisation avec des appareils de perfusion sous pression

Reference number
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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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 8536-8 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical 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, 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 equipment for use with pressure infusion apparatus*

— *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 8:
Infusion equipment for use with pressure infusion apparatus

1 Scope

This part of ISO 8536 gives users information on sterilized infusion sets for single use with pressure infusion equipment up to a maximum of 200 kPa (2 bar).

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 594-2:1998, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

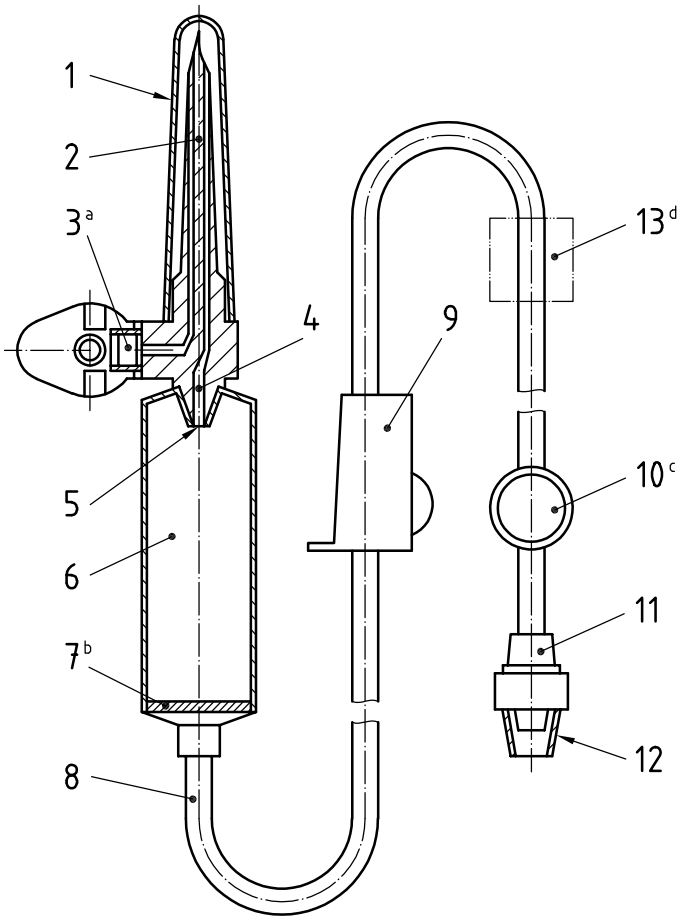
ISO 8536-4:2004, *Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed*

ISO 15223*, Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

IEC 60601-2-24, *Medical electrical equipment — Part 2-24: Particular requirements for the safety of infusion pumps and controllers*

3 General requirements

3.1 The nomenclature to be used for components of infusion sets and of a separate air-inlet device is given in Figures 1, 2 and 3. These figures illustrate examples of the configuration of infusion sets and air-inlet devices; other configurations may be used provided they lead to the same results. Infusion sets as illustrated in Figure 2 should only be used for collapsible plastics containers. Infusion sets as illustrated in Figure 2 used with separate air-inlet devices as illustrated in Figure 3, or infusion sets as illustrated in Figure 1 shall be used for rigid containers.



Key

1	protective cap of closure-piercing device	8	tubing
2	closure-piercing device	9	flow regulator
3	air-inlet with air filter and closure	10	injection site
4	fluid channel	11	male conical fitting
5	drip tube	12	protective cap of male conical fitting
6	drip chamber	13	flow element
7	fluid filter		

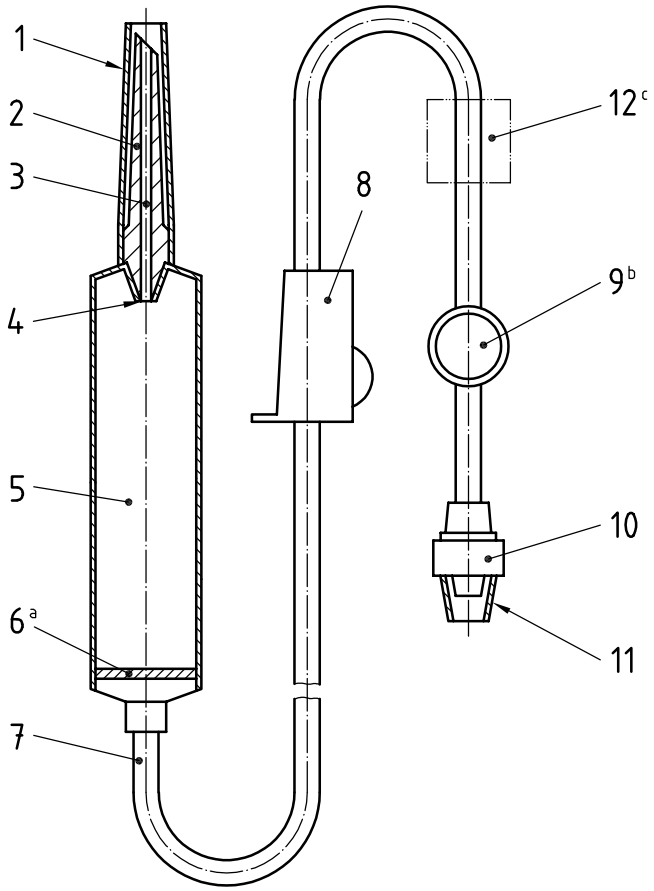
[a] Closure of air inlet is optional.

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

[c] Injection site is optional.

[d] Optional element of infusion set which interfaces with pressure infusion equipment.

Figure 1 — Example of a vented infusion set



Key

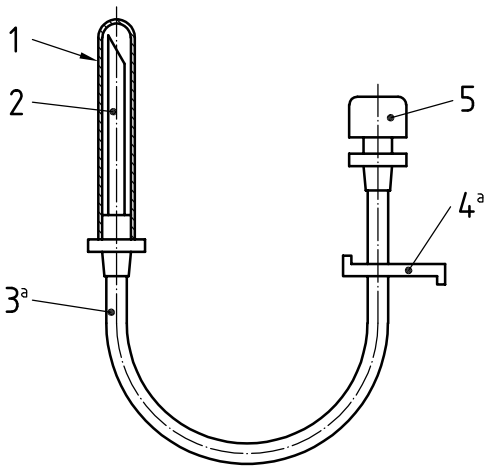
1	protective cap of the closure-piercing device	7	tubing
2	closure-piercing device	8	flow regulator
3	fluid channel	9	injection site
4	drip tube	10	male conical fitting
5	drip chamber	11	protective cap of the male conical fitting
6	fluid filter	12	flow element

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

[b] Injection site is optional.

[c] Optional element of infusion set which interfaces with pressure infusion equipment.

Figure 2 — Example of a non-vented infusion set



Key

1	protective cap	4	clamp [a]
2	closure-piercing device or needle	5	air-inlet with air filter
3	tubing		

[a] Other designs are acceptable if the same safety aspects are ensured.

Figure 3 — Example of an air-inlet device

3.2 The infusion set shall be provided with protective caps to maintain sterility of the internal parts of the set until the set is used. The air-inlet device shall be provided with a protective cap over the closure-piercing device or needle.

4 Designation

4.1 Infusion set

Infusion sets complying with the requirements specified in this part of ISO 8536 shall be designated by the descriptor words, followed by a reference to this part of ISO 8536, followed by the letters IS, followed by the letter P:

Infusion set ISO 8536-8 — IS — P

4.2 Air-inlet device

Air-inlet devices complying with the requirements specified in this part of ISO 8536 shall be designated by the descriptor words, followed by a reference to this part of ISO 8536, followed by the letters AD.

Air-inlet device ISO 8536-8 — IS — AD

5 Materials

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

6 Physical requirements

6.1 Particulate contamination

ISO 8536-4 applies.

6.2 Tensile strength

When tested as specified in A.2, the infusion set, excluding protective caps, shall withstand a static tensile force of not less than 15 N for 15 s.

6.3 Leakage

The infusion set shall be impermeable to air, microorganisms and fluids.

Neither air nor water shall escape when tested according to A.3.2 and A.3.4, and no air shall enter when tested according to A.3.3.

6.4 Male conical fitting

The male conical fitting must be in accordance with ISO 594-2. No water shall leak from the point of connection when tested according to A.4.

6.5 Injection site

The injection site shall enable injection into the tubing. There shall be no leakage of more than one falling drop of water when tested according to A.5.

6.6 Fluid filter

ISO 8536-4 applies.

6.7 Flow rate of infusion fluid

ISO 8536-4 applies.

6.8 Closure-piercing device

ISO 8536-4 applies.

6.9 Air-inlet device

ISO 8536-4 applies.

6.10 Drip chamber and drip tube

ISO 8536-4 applies.

6.11 Tubing

ISO 8536-4 applies.

6.12 Flow regulator

ISO 8536-4 applies.

6.13 Protective caps

ISO 8536-4 applies.

6.14 Storage volume

The storage volume shall be determined according to IEC 60601-2-24 and shall be stated according to 10.1 h).

7 Chemical requirements

ISO 8536-4 applies.

8 Biological requirements

ISO 8536-4 applies.

9 Packaging

ISO 8536-4 applies.

10 Labelling

10.1 Unit container

The unit container shall be labelled with the following minimum information:

a) a textual description of the contents;

b) indication that the infusion set is sterile, using the graphical symbol as given in ISO 15223;

c) indication that the infusion set is free from pyrogens, or that the infusion set is free from bacterial endotoxins;

d) indication that the infusion set is for single use only, or equivalent wording, or using the graphical symbol according to ISO 15223;

e) instructions for use, including warnings, e.g. about detached protective caps (instructions for use may also take the form of an insert);

f) the lot (batch) designation, prefixed by the word LOT, or using the graphical symbol according to ISO 15223;

g) year and month of expiry, accompanied by appropriate wording or the graphical symbol according to ISO 15223;

h) the wording “Safe for use with pressure infusion equipment. Storage volume at 40 °C ..... ml.” (The name and type of pressure infusion equipment, as well as the storage volume, shall be given by the manufacturer.);

i) identification block of designation according to Clause 3 (**ISO 8536-8 — IS — P**);

j) letter “P”, which stands for pressure, and whose type height shall stand out clearly from surrounding text;

k) a statement that 20 drops of distilled water or 60 drops of distilled water delivered by the drip tube are equivalent to a volume of (1 ± 0,1) ml or a mass of (1 ± 0,1) g;

l) name or logo and address of manufacturer or supplier.

10.2 Shelf or multi-unit container

The shelf or multi-unit container shall be labelled with the following minimum information:

a) a textual description of the contents;

b) the lot (batch) designation, prefixed by the word LOT, or using the graphical symbol according to ISO 15223;

c) identification block of designation according to Clause 3 (**ISO 8536-8 — IS — P**);

d) letter “P”, which stands for pressure, and whose type height shall stand out clearly from surrounding text;

e) instructions for use, including warnings, e.g. about detached protective caps (instructions for use may also take the form of an insert);

f) year and month of expiry, accompanied by appropriate wording or the graphical symbol according to ISO 15223;

g) storage note.

Annex A
(normative)

Physical tests

A.1 Test for particulate contamination

ISO 8536-4 applies.

A.2 Test of tensile strength

Expose the infusion set to be tested to a static tensile force of 15 N applied along the longitudinal axis for 15 s. Inspect whether the infusion set withstands the test force applied.

A.3 Tests for leakage

A.3.1 In the beginning of the test, condition the whole system at the test temperature.

A.3.2 Connect the infusion set with the air supply and close all other openings. Apply air with an internal excess pressure of 50 kPa at (23 ± 1) °C and (40 ± 1) °C to the fluid lines for 15 s. Inspect the infusion set for any leakage of air under water.

A.3.3 Fill the infusion set with degassed, distilled water, connect it with its openings sealed to a vacuum device and subject it to an internal excess pressure of − 20 kPa at (23 ± 1) °C and (40 ± 1) °C for 15 s. Atmospheric pressure shall be the reference pressure. Excess pressure, according to ISO 31-3, can assume positive or negative values. Inspect whether air enters the infusion set.

A.3.4 The water-filled section of the infusion set below its flow element is tested for 15 min under the maximum operating pressure of the pump with which it is designed to be used. The maximum internal excess pressure of the infusion set should not exceed 200 KPa.

A.4 Testing of male conical fitting for leakage

In the beginning of the test, condition the whole system at the test temperature.

Close the male conical fitting of the adapter with the reference connector as specified in ISO 594-2. Test the conical connection for 15 min, using distilled water under an internal excess pressure of 200 kPa at (23 ± 1) °C and (40 ± 1) °C. Inspect the point of connection for leakage of water.

A.5 Test of injection site

Perform according to ISO 8536-4, but under internal excess pressure of 200 kPa.

A.6 Test for efficiency of the fluid filter

ISO 8536-4 applies.

Annex B
(normative)

Chemical tests

ISO 8536-4 applies.

Annex C
(normative)

Biological tests

ISO 8536-4 applies.

Bibliography

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[3] ISO 11134:1994, *Sterilization of health care products — Requirements for validation and routine control — Industrial moist heat sterilization*

[4] ISO 11135:1994, *Medical devices — Validation and routine control of ethylene oxide sterilization*

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[6] European Pharmacopoeia

[7] United States Pharmacopeia

ICS 11.040.20

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