INTERNATIONAL STANDARD

ISO 8536-8

Redline version
compares Second edition to
First edition

Infusion equipment for medical use —

Part 8:
Infusion sets for single use with pressure infusion apparatus

Matériel de perfusion à usage médical —

Partie 8: Appareils de perfusion non réutilisables avec des appareils de perfusion sous pression

Reference number
ISO 8536-8:redline:2015(E)

IMPORTANT — PLEASE NOTE

This is a mark-up copy and uses the following colour coding:

Text example 1	— indicates added text (in green)
~~Text example 2~~	— indicates removed text (in red)
	— indicates added graphic figure
	— indicates removed graphic figure
1.x ...	— Heading numbers containg modifications are highlighted in yellow in the Table of Contents

All changes in this document have yet to reach concensus by vote and as such should only be used internally for review purposes.

DISCLAIMER

This Redline version provides you with a quick and easy way to compare the main changes between this edition of the standard and its previous edition. It doesn't capture all single changes such as punctuation but highlights the modifications providing customers with the most valuable information. Therefore it is important to note that this Redline version is not the official ISO standard and that the users must consult with the clean version of the standard, which is the official standard, for implementation purposes.

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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~~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 documents should be noted. This document was drafted in accordance with the ~~rules given in~~editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

~~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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

~~ISO 8536-8 was prepared by Technical Committee~~The committee responsible for this document is ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This second edition cancels and replaces the first edition (ISO 8536-8:2004), which has been technically revised with the following changes:

— The part title has been changed from 'Infusion equipment ...' to 'Infusion sets ...';

— The former Clause 4 on designation has been deleted;

— 6.14 has been amended and an appropriate Annex B 'Storage volume' added;

— Clause 10 on labelling was amended by a note regarding the usage of the symbol "XXX" according ISO 7000-2725;

— Clause 11 on disposal has been added;

— A.3 'Tests for leakage' has been amended;

— The former A.4 specifying a test of male conical fitting for leakage has been deleted;

— Normative references and the Bibliography have been updated;

— Document has been editorially 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 ~~equipment~~sets for single use with pressure infusion apparatus*

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

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

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

— *Part 12: Check valves*

The following parts are under preparation:

— *Part 13: Graduated flow regulators for single use with infusion sets*

— *Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact*

Infusion equipment for medical use —

Part 8:
Infusion sets for single 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~~apparatus up to a maximum of 200 kPa (2 bar).

In some countries, the 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~~documents, in whole or in part, are normatively referenced in this document and are indispensable for ~~the application of this document~~its application. 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~~ [1], *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

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

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

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

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

NOTE These terms and definitions are specifically applicable to Annex B.

3.1
filling volume
VF
volume of tube during „pressure less“-filling respectively filling by gravity, the tube remains unstressed

Note 1 to entry: The filling volume is to be equated with the calculated volume of the tube.

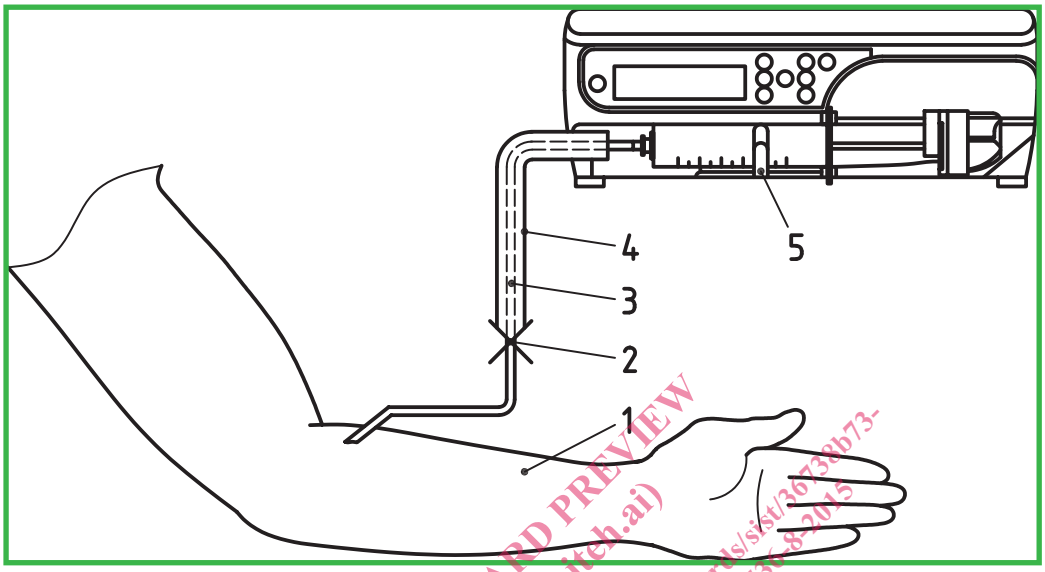
3.2
storage volume
VS
tube volume during pressurization equal to filling volume (V_F) plus bolus volume (V_S):

$$V_S = V_F + V_B$$

1) To be replaced by ISO 80369-7.

3.3
bolus volume
VB
increased tube volume during pressurization (storage volume V_S) in comparison to the unstressed tube (filling volume V_F)

Note 1 to entry: For illustration of the bolus volume see Figure 1.



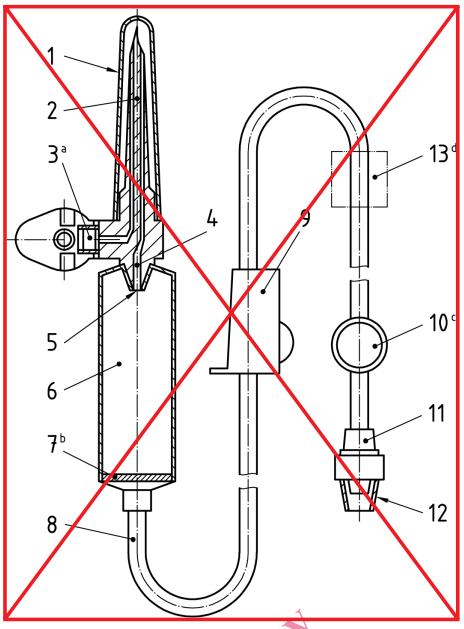
Key

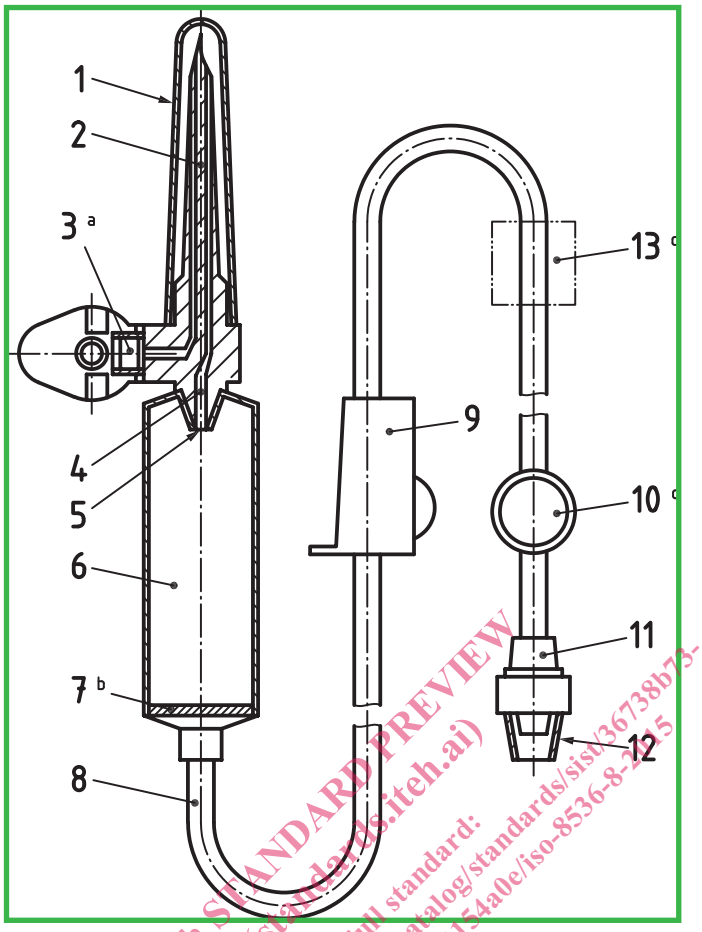
1	patient	4	bolus volume
2	occlusion	5	syringe pump
3	tube		

Figure 1 — Bolus volume

~~3~~4 General requirements

~~3.1~~**4.1** The nomenclature to be used for components of infusion sets and of a separate air-inlet device is given in Figures ~~1~~2, ~~2~~3, and ~~3~~4. 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~~3 should only be used for collapsible plastics containers. Infusion sets as illustrated in Figure ~~2~~3 used with separate air-inlet devices as illustrated in Figure ~~3~~4, or infusion sets as illustrated in Figure ~~1~~2 shall be used for rigid containers.





Key

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

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 apparatus.

Figure ~~1~~ 2 — Example of a vented infusion set