INTERNATIONAL STANDARD

ISO 8536-9

Redline version
compares Second edition to
First edition

Infusion equipment for medical use —

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

Matériel de perfusion à usage médical —

Partie 9: Tubulures non réutilisables avec des appareils de perfusion sous pression

Reference number
ISO 8536-9: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 8536-9 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 8536-9:2004), which has been technically revised with the following changes:

— The former Clause 3 on designation has been deleted;

— 5.8 has been amended and an appropriate Annex C has been added;

— Clause 9 on labelling was amended by addition of information regarding the usage of the symbol "XXX" according ISO 7000, symbol 2725;

— Clause 10 on disposal has been added;

— A.4 has been amended;

— The former A.5 specifying a test for leakage of adapters with female and/or male conical fittings 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 9:
Fluid lines for single use with pressure infusion equipment

1 Scope

This part of ISO 8536 applies to sterilized fluid lines for single use for use with pressure infusion equipment up to a maximum of 200 kPa (2 bar).

The following items are covered by this part of ISO 8536:

a) syringe pump lines (SPL);

b) connecting lines (CL);

c) lines with integrated injection cannula (LIC).

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,[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 7864, *Sterile hypodermic needles for single use*

ISO 8536-4:~~2004~~2010, *Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed*

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

ISO 8536-11, *Infusion equipment for medical use — Part 11: Infusion filters for single use with pressure infusion equipment*

ISO 10993-4, *Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood*

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*~~

1) To be replaced by ISO 80369-7.

3 ~~Designation~~ Termes and definitions

~~The designation of a syringe pump line (SPL) for infusions under pressure (P) is as follows:~~For the purposes of this document, the following terms and definitions apply.

~~**Pump line** ISO 8536-9 — SPL — P~~

~~The designation of a connecting line (CL) for infusions under pressure (P) is as follows.~~

~~**Connecting line** ISO 8536-9 — CL — P~~

~~The designation of a line with injection cannula (LIC) for infusions under pressure (P) is as follows.~~

~~**Cannular line** ISO 8536-9 — LIC — P~~

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

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

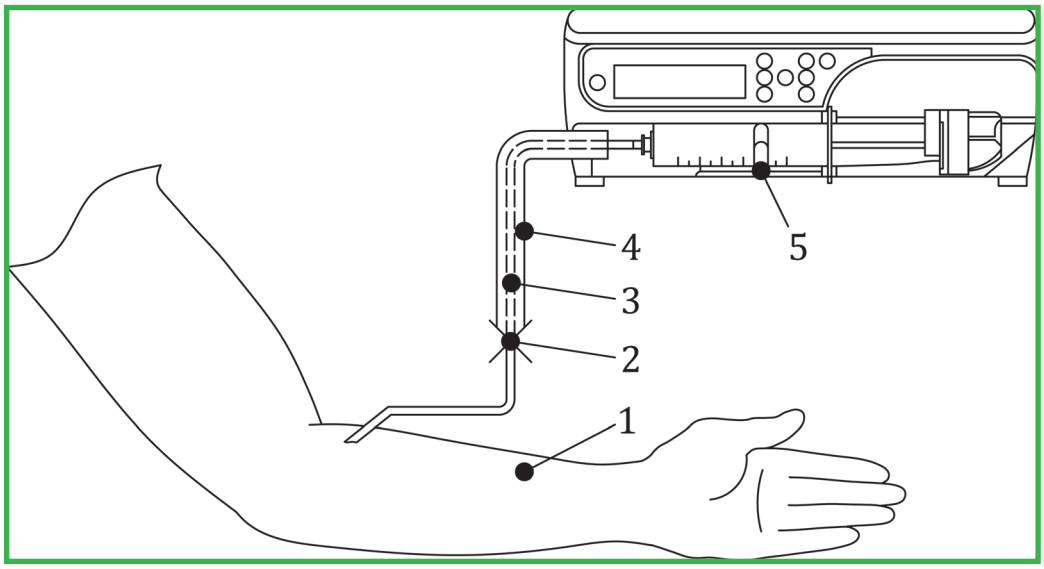
Note 1 to entry: The filling volume is to be equated with the calculated volume of the tube.

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

$$V_S = V_F + V_B$$

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
2 occlusion
3 tube
4 bolus volume
5 syringe pump

Figure 1 — Bolus volume

4 Materials

The materials from which the fluid lines ~~as given in Clause 3~~ are manufactured shall comply with the requirements as specified in ~~Clauses~~ Clause 5, Clause 6, and Clause 7.

5 Physical requirements

5.1 Transparency

Tubing of fluid lines shall be transparent. When tested as specified in A.1, the air-water interface shall be detectable.

5.2 Particulate contamination

The fluid lines shall be manufactured under conditions that minimize particulate contamination. The fluid pathway surfaces shall be smooth and clean. When tested as specified in A.2, the number of particles shall not exceed the contamination index.

5.3 Tensile strength

When tested as specified in A.3, all parts of a fluid line shall withstand a static tensile force of at least 15 N for ~~15s~~15 s.

5.4 Leakage

In the beginning of the test, the whole system shall be conditioned at the test temperature.

The fluid lines shall be impermeable to air, microorganisms, and fluids. When tested as specified in A.4, there shall be no leakage of air or water.

5.5 Adapters with female and/or male conical fittings

In the beginning of the test, the whole system shall be conditioned at the test temperature.

Adapters shall be provided with a connector with female conical fitting and/or a connector with male conical fitting according to ISO 594-2. ~~When tested as specified in A.5, no water shall leak from the point of connection.~~

5.6 Accessories

Accessories of fluid lines, other than infusion filters, shall comply with the requirements as specified in ISO 8536-10.

5.7 Filters

Infusion filters shall comply with the requirements as specified in ISO 8536-11.

5.8 Storage volume

The storage volume shall be ~~determined in accordance with IEC 60601-2-24 and shall be stated according to~~stated according to 9.2 i). For a definition of the storage volume and for a test method for the determination of the storage volume, see ~~9.1 g)~~Annex C.

5.9 Injection needles

Injection needles shall comply with ISO 7864 when tested as specified in A.~~6~~5.

5.10 Protective caps

ISO 8536-4 applies.

6 Chemical requirements

ISO 8536-4 applies. For test methods, see Annex B.

7 Biological requirements

7.1 Sterility

The fluid lines in their unit container shall have been subjected to a validated sterilization process (see Reference [~~Bibliography~~2] to Reference [5]).

7.2 Pyrogens

The fluid lines shall be assessed for freedom from pyrogens using a suitable test and the results shall indicate that the fluid lines are free from pyrogens. Guidance on testing for pyrogenicity is given in ISO 8536-4.

7.3 Haemolysis

The fluid lines shall be assessed for freedom from haemolytic constituents and the result shall indicate that the fluid lines are free from haemolytic reactions.

Guidance on testing for haemolytic constituents is given in ISO 10993-4.

