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Transfuzijska oprema za uporabo v medicini - 5. del: Transfuzijske garniture za enkratno uporabo s tlačno črpalko (ISO/DIS 1135-5:2023)

Transfusion equipment for medical use - Part 5: Transfusion sets for single use with pressure infusion apparatus (ISO/DIS 1135-5:2023)

Transfusionsgeräte zur medizinischen Verwendung - Teil 5: Transfusionsgeräte zur einmaligen Verwendung mit Druckinfusionsapparaten (ISO/DIS 1135-5:2023)

Matériel de transfusion à usage médical - Partie 5: Transfuseurs non réutilisables avec des appareils de perfusion sous pression (ISO/DIS 1135-5:2023)

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Transfusion equipment for medical use —

Part 5:
Transfusion sets for single use with pressure infusion apparatus

Matériel de transfusion à usage médical —

Partie 5: Appareils de transfusion non réutilisables avec les appareils de perfusion sous pression

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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.

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 editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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).

This second edition of ISO 1135-5 cancels and replaces the first edition (ISO 1135-5:2015), which has been technically revised with the following changes:

— the definitions of the different ‘volume’ terms have been amended;

— 6.10 “Injection site” has been amended in regard of the use of needle-free injection ports and Luer-activated devices;

— 6.12 “Protective caps” has been more clarified how to prevent contamination;

— 6.13 has been completely revised and renamed to clarify the described volume;

— Clause 9 “Labelling” has been updated especially in regard of the referenced ISO 15223-1;

— Clause 10 “Packaging” has been amended by a reference to ISO 11607-1;

— Annex A “Physical test” has been amended by a general introduction on the pre-conditioning. In addition the description of the test for leakage has been extended;

— Annex D on ‘Storage volume’ has been renamed to ‘Determination of tube volumes’ and revised; D.3 on ‘Labelling’ has been deleted;

— the Normative references have been updated;

— some minor editorial changes were introduced in the whole document.

A list of all parts in the ISO 1135 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.

Transfusion equipment for medical use —

Part 5:
Transfusion sets for single use with pressure infusion apparatus

1 Scope

This document specifies requirements for single use transfusion sets for use with pressure infusion equipment capable of generating pressures up to 200 kPa (2 bar). This International Standard ensures compatibility with containers for blood and blood components as well as intravenous equipment.

Secondary aims of this document are to provide guidance on specifications relating to the quality and performance of materials used in transfusion sets, to present designations for transfusion set components, and to ensure the compatibility of sets with red cell and plasma blood components.

Platelet components should not be transfused under pressure using these sets.

NOTE In some countries, the national pharmacopoeia or other national regulations are legally binding and take precedence over this document.

2 Normative references

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.

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 3826-1:2019, *Plastics collapsible containers for human blood and blood components — Part 1: Conventional containers*

ISO 3826-2, *Plastics collapsible containers for human blood and blood components — Part 2: Graphical symbols for use on labels and instruction leaflets*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 14644-1, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration*

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

ISO 80369-20, *Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods*

3 Terms and definitions

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

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/

3.1
filling volume
V_F
volume of tube during “pressureless” filling, respectively filling by gravity downstream of the infusion pump

Note 1 to entry: The tube remains unstressed.

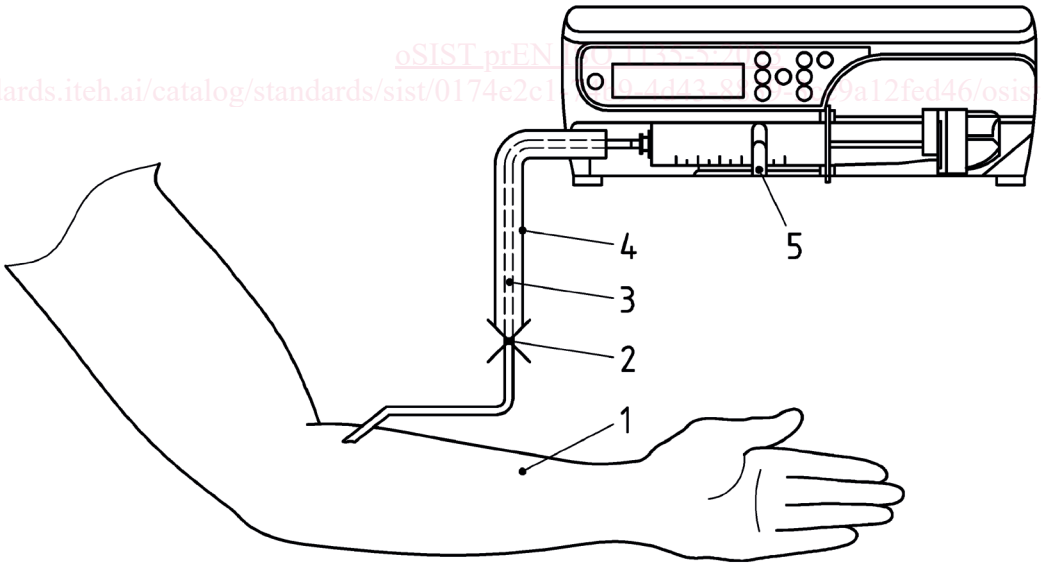
Note 2 to entry: The filling volume is to be equated with the calculated volume of the tube.

3.2
storage volume
V_S
tube volume during pressurization downstream of the infusion pump

3.3
post-occlusion bolus volume
V_B
increased tube volume downstream of the infusion pump during pressurization in comparison with the unstressed tube

Note 1 to entry: V_B equals to $V_S - V_F$ considering that for V_S and V_F the tubes have the same length.

Note 2 to entry: For illustration of the post-occlusion bolus volume, see Figure 1.



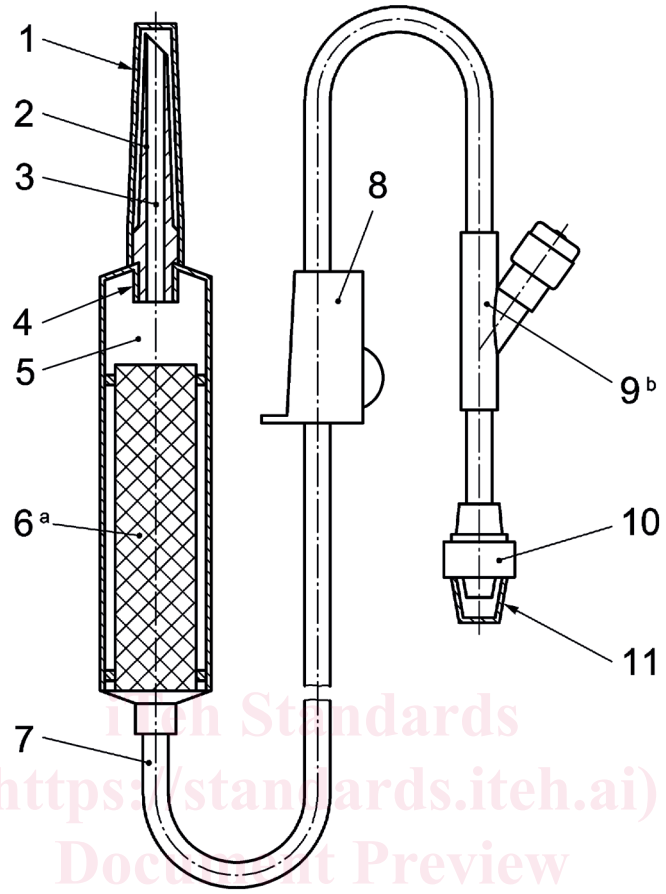
Key

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

Figure 1 — Post-occlusion bolus volume

4 General requirements

4.1 The nomenclature for components of transfusion sets is given in Figure 2.



Key

1	protective cap of the closure-piercing device	8	flow regulator
2	closure-piercing device	9	injection site
3	fluid channel	10	male conical fitting
4	drip tube	11	protective cap of the male conical fitting
5	drip chamber	a	Indicates alternative locations of the filter for blood and blood components. Other designs are acceptable if the same safety aspects are ensured.
6	filter for blood and blood components	b	Injection site is optional.
7	tubing		

Figure 2 — Example of a transfusion set

4.2 The transfusion set shall be provided with protective caps.

5 Materials

The materials from which the transfusion sets given in Clause 4 are manufactured shall comply with the requirements specified in Clause 6. If components of the transfusion set come into contact with blood and blood components, they shall additionally comply with the requirements specified in Clauses 7 and 8.