International Standard

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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: Transfuseurs non réutilisables avec des appareils de perfusion sous pression

Reference number
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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 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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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 cancels and replaces the first edition (ISO 1135-5:2015), which has been technically revised.

The main changes are as follows:

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

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

— 6.13 “Protective caps” has been amended to clarify how to prevent contamination;

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

— Clause 8 has been revised to meet state-of-the-art methodology:

  — biological risk assessment shall follow ISO 10993-1;

  — sterility subclause remains;

  — subclause on hemocompatibility assessment has been revised;

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

— Clause 10 “Packaging” has been amended by adding 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 C “Biological tests” has been deleted;

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— the former Annex D (now Annex C) has been revised; it has been renamed from "Storage volume" to "Determination of tube volumes", and the subclause D.3 "Labelling" has been deleted;

— the Normative references have been updated.

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.

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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. It ensures compatibility with containers for blood and blood components as well as intravenous equipment.

This document also provides 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.

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

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

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

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

ISO 10993-4:2017, *Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood*

ISO 10993-12, *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials*

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*

1) As impacted by ISO 3826-1:2019/Amd 1:2023

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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 without any additional pressure.

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.

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