International Standard

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Second edition
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Infusion equipment for medical use —

Part 13: Graduated flow regulators for single use with fluid contact

Matériel de perfusion à usage médical —

Partie 13: Régulateurs de débit gradués non réutilisables avec contact à fluide

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Foreword

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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).

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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 edition cancels and replaces the first edition (ISO 8536-13:2016), which has been technically revised.

The main changes are as follows:

— in Clause 3, the new term “activation” has been added;

— Figure 1 in Clause 4 has been amended to include markings on the open and close positions;

— former Clause 8 “Biological requirements” has been deleted due to the specified product being non-sterile;

— Annex A has been amended by a general introduction (see A.1) on the pre-conditioning of the sample;

— Annex A.5 has been amended to align the flow rate test method with other flow rate test methods in the ISO 8536 series;

— the Bibliography has been updated.

A list of all parts in the ISO 8536 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.

Infusion equipment for medical use —

Part 13:
Graduated flow regulators for single use with fluid contact

1 Scope

This document specifies requirements for non-sterile, single-use graduated flow regulators used as subcomponents in sterilized infusion sets for single use to control the flow of intravenous infusion solutions with fluid contact under gravity feed conditions.

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

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

ISO 80000-4, *Quantities and units — Part 4: Mechanics*

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
graduated flow regulator
GFR
subcomponent with graduation and with fluid contact for setting certain flow of liquids

3.2
flow rate
volume per time

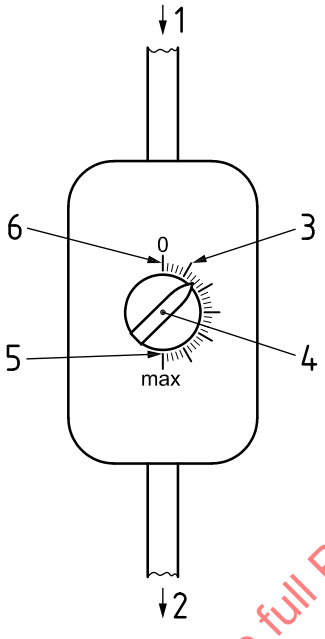
3.3
scale
array of marks, together with any associated figuring, in relation to which the position of the pointer is observed

3.4
activation
sequence of engaging the GFR from the open to the closed position then returning to the open position

4 Design

The GFR shall be designed for a constant flow regulation. When tested as specified in A.5.3, the stability of flow rate shall be at least within ±10 % during the test time. The GFR shall be designed for a safe use to avoid accidental change of flow rate and shall clearly indicate open and closed positions.

A typical design for a GFR is shown in Figure 1.



Key

1 upstream
2 downstream
3 scale
4 pointer
5 open position
6 closed position

Figure 1 — Example for the design of a GFR (schematic)

5 Materials

The materials used shall conform with the requirements specified in Clauses 6 and 7. In addition, the materials of all items described shall be assessed in accordance with the requirements of ISO 10993-1.

6 Physical requirements

6.1 Graduated scale

The scale shall indicate open and closed positions of the GFR plus scale positions as defined by the manufacturer.

6.2 Particulate contamination

The GFR shall be manufactured under conditions that minimize particulate contamination. The inner surface shall be smooth and clean. When tested as specified in A.2, after pre-conditioning in accordance with the general and specific conditions described in A.1, the number of particles shall not exceed the contamination index.

6.3 Tensile strength

When tested as specified in A.3, after pre-conditioning in accordance with the general conditions described in A.1, the GFR shall withstand a static longitudinal tensile force of not less than 15 N for 15 s.

6.4 Leakage

6.4.1 The GFR shall be tight in the open and closed positions and all other positions between open and closed. When tested as specified in A.4.1 and A.4.3, after pre-conditioning in accordance with the general and specific conditions described in A.1, there shall be no leakage.

6.4.2 In the closed position, the GFR shall close the line that there is no leakage between downstream and upstream. When tested as specified in A.4.2, after pre-conditioning according to the general and specific conditions described in A.1, there shall be no leakage.

6.5 Flow rates

The GFR shall deliver flow rates according to scale settings. When tested as specified in A.5, after pre-conditioning in accordance with the general and specific conditions described in A.1, the GFR shall deliver this flow rate as specified by the manufacturer within given tolerances.

7 Chemical requirements

The chemical requirements shall be in accordance with ISO 8536-4.

Annex A
(normative)

Physical tests

A.1 General

A.1.1 All physical tests shall be performed at a temperature of (23 ± 2) °C unless other temperatures are given in the test method. To ensure repeatable test results, at the beginning of the test, the samples shall be conditioned to (23 ± 2) °C unless other temperatures are given in the following test methods.

A.1.2 Prior to all physical tests, the GFR shall be preconditioned.

General preconditioning factors to consider include, but are not limited to, sterilisation stresses (temperature/humidity), transportation stresses (temperature/vibration), component ageing, and use with a pump.

Specific preconditioning factors shall be included to ensure the performance requirements of the GFR shall meet the later intended use of the finished medical device. In addition to the general preconditioning factors, specific preconditioning factors to be included is the number of GFR activations over a device lifetime.

A.2 Test for particulate contamination

Perform the test as specified in ISO 8536-4.

A.3 Test for tensile strength

Expose the GFR to be tested to a static longitudinal tensile force of 15 N for 15 s. Inspect whether points of connection and components withstand the test force applied.

A.4 Tests for leakage

A.4.1 Set the GFR in open position and connect it with one end closed to a compressed air supply. Immerse the GFR, with one end blocked, in water at (40 ± 1) °C and apply air with an internal excess pressure of 50 kPa to the GFR. Inspect the GFR for any leakage of air in open position for 15 s. Repeat the test at positions 25 %, 50 % and 75 % of scale.

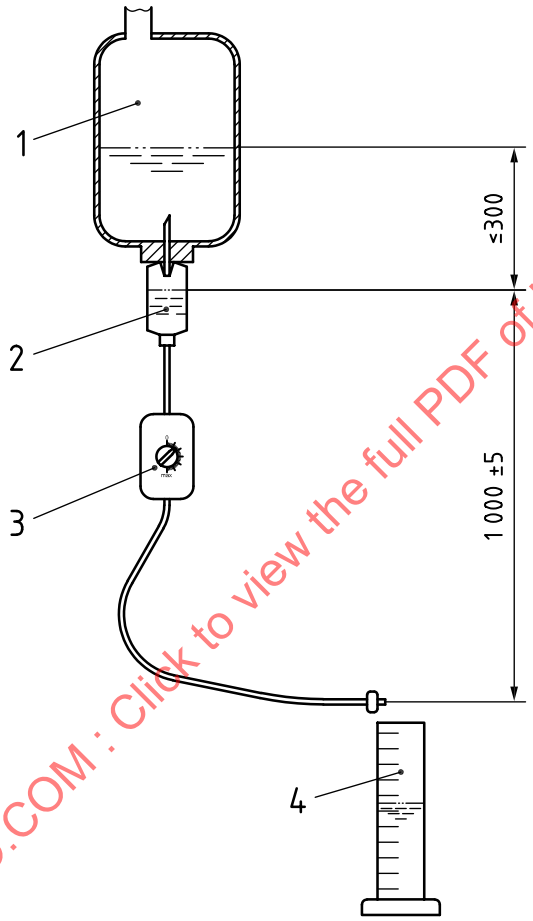
A.4.2 Set the GFR in closed position and connect one end to a compressed air supply and leave the other end open. Immerse the open end of the GFR in water at (40 ± 1) °C and apply air with an internal excess pressure of 50 kPa to the GFR for 15 s. Inspect the open end of the GFR for any leakage of air. Finally, close the open end of the tube; keep the test sample under 50 kPa pressure and inspect for any leakage of air coming from the GFR.

A.4.3 Fill an infusion set with integrated GFR with setting open position 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 (40 ± 1) °C for 15 s. Atmospheric pressure shall be the reference pressure. Excess pressure, in accordance with ISO 80000-4, can assume positive or negative values. Ascertain whether air enters the infusion set. Repeat this test with GFR in position closed for another 15 s and continue to do it at 25 %, 50 % and 75 % of scale positions for the same time.

A.5 Determination of flow rate

A.5.1 Use a container or a bag filled with min 1 000 ml of sodium chloride solution [concentration of NaCl = 9 g/l] and conditioned to (23 ± 2) °C. If a rigid or semi-rigid container is used, the container shall be cut open at the top to provide a freely vented system. Connect the GFR to an existing gravity set or select a gravity infusion set with an integrated GFR. Insert the closure-piercing device of the infusion set into the container or bag port. Fill the drip chamber to be approximately ⅔ full. Open the GFR and fill the complete infusion set. Close the GFR. Arrange the test setup so that there is a height of (1 000 ± 5) mm between the liquid level of the drip chamber and the outlet of the infusion set at the beginning of the test. The liquid level between that in the drip chamber and the container or bag shall not exceed 300 mm (see Figure A.1).

Dimensions in millimetres



Key

1 container or bag
2 drip chamber
3 GFR
4 measuring cylinder

Figure A.1 — Example test setup to determine the flow rate (schematic)

A.5.2 Test the flow rate in three different positions of the scale: low, medium, and high settings. Measuring time shall be appropriate for the selected flow rates. The flow rate accuracy shall be according to the specification of the manufacturer.

A.5.3 Set the GFR at a medium position. Start the test and run for 15 min for stabilization followed by 6 consecutive hours and read the volume collected every hour. The stability of flow rate shall be at least within ±10 % during the test time.