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Infusion equipment for medical use —

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

Matériel de perfusion à usage médical —

Partie 14: Clamps et limiteurs de débit pour appareils de transfusion et de perfusion sans 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 on 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 the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

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 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*

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

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

Infusion equipment for medical use —

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

1 Scope

This part of ISO 8536 specifies requirements for non-sterile clamps and flow regulators used as a subcomponent to control the flow of intravenous solutions and/or blood components through sterilized infusion and blood transfusion sets and blood bag assemblies without fluid contact.

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 documents, in whole or in part, are normatively referenced in this document and are indispensable for 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 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

3 Terms and definitions

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

3.1
clamp
subcomponent applied externally to an infusion/transfusion equipment without fluid contact with an "on/off" function used to terminate or initiate the flow of fluid through the line

3.2
flow regulator
subcomponent with or without graduation applied externally to an infusion/transfusion equipment without fluid contact to control the flow of fluid through the line

3.3
flow rate
volume per time

4 Design

Clamps and flow regulators shall be designed for their application in controlling fluid transfer in infusion/transfusion equipment. These devices shall be designed for safe use, avoiding accidental operation, and shall not puncture or damage the flexible tubing during their operation.

Typical design for clamps and flow regulators is shown in Figures 1 to 3.

Figure 1 — Design of a pinch clamp (schematic)

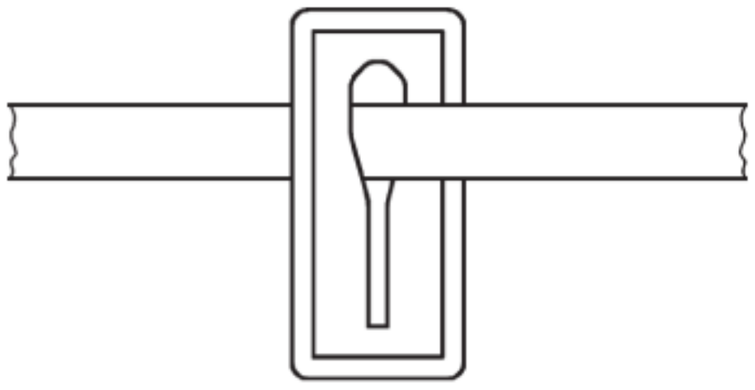

Figure 2 — Design of a slide clamp (schematic)

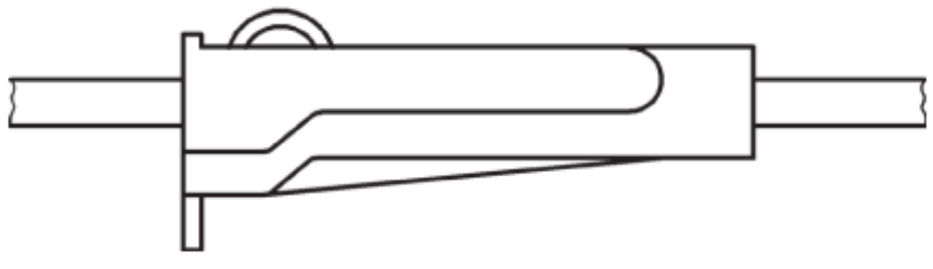

Figure 3 — Design of a flow regulator (known as roller clamp) (schematic)

5 Materials

The materials used shall comply with the requirements specified in Clause 6. In addition, the materials of all items described shall be assessed to the requirements of ISO 10993-1.

6 Physical requirements

6.1 Tubing specifications

Clamps and flow regulators shall be capable of operating with flexible tubing within the range of external diameter, wall thickness and characteristics for which they are designed to be used.

NOTE Tubing attached to infusion/transfusion sets and blood bags is typically within the external diameter range 3,0 mm to 4,5 mm with a wall thickness of 0,4 mm to 0,6 mm. For neonatal and specific applications, this can differ considerably.

6.2 Operating temperature

Clamps and flow regulators shall be capable of operating with flexible tubing in a temperature range suitable for the application of the medical device.

6.3 Construction

Clamps and flow regulators shall accommodate the flexible tubing within a channel, slot or other suitable design in order to ensure that the entire external diameter of the tube is consistently restricted and fluid flow can be completely occluded during closure.

Clamps shall be designed either as “temporary” or “permanent,” depending on their mode of action upon initial closure of the device. They shall be capable of locking with no more than one movement in a single plane. The clamps shall, when closed, resist the flow of fluid and air at an applied pressure of 50 kPa (see A.1).

Permanent clamps shall be

— tamperproof, and

— clearly distinguishable from temporary clamps (e.g. by colour coding).

Temporary clamps shall be

— re-openable (non-accidentally) by no more than two movements of its subcomponent parts,

— capable of being operated through defined cycles of opening and closure, and

— clearly distinguishable from permanent clamps (e.g. by colour coding).

6.4 Flow rates

The flow regulator shall adjust the flow of the fluid between zero and the maximum. The flow regulator should be capable of continuous use throughout an application without the tubing being damaged. There should be no deleterious reaction between the flow regulator and the tubing when they are stored in such a way that there is contact.

For flow regulators without fluid contact with graduation, testing shall be performed in accordance with A.2.

Annex A
(normative)

Physical tests

A.1 Pressure test

A.1.1 In the beginning of the test, condition the whole system at the test temperature.

A.1.2 Set the clamp or flow regulator in the "Open" position and fit it to a line of the appropriate dimensions for the device with both ends open and connect the upstream end to a compressed air supply.

A.1.3 Fully close the clamp or flow regulator. Immerse the line and clamp or flow regulator in water at (40 ± 1) °C and apply air with an internal excess pressure of 50 kPa for 15 s to one end of the tube. Inspect the open end for any leakage of air.

A.1.4 If required by application, repeat test A.1.3 in water at the appropriate temperature and inspect the open end for any leakage of air.

A.2 Determination of flow rate for flow regulator with graduation

A.2.1 Apply the flow regulator to an existing gravity infusion set or use a gravity infusion set with flow regulator integrated and condition at test temperature (23 ± 2) °C.

A.2.2 Prepare a container filled with sodium chloride solution [concentration (NaCl) = 9 g/l] at (23 ± 2) °C.

A.2.3 Pre-set the hydrostatic pressure at 1 m.

A.2.4 Prime the gravity infusion set while flow regulator is in "Open" position. 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.2.5 Prepare a container with sodium chloride solution [concentration (NaCl) = 9 g/l] and a gravity infusion set with flow regulator. Set the flow regulator at a medial position. Use a hydrostatic pressure of 1 m. 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.

Bibliography

[1] ISO 1135 (all parts), *Transfusion equipment for medical use*

[2] ISO 3826 (all parts), *Plastics collapsible containers for human blood and blood components*

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

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