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Intravascular catheters — Sterile and single-use catheters —

Part 8: Catheters for extracorporeal blood treatment

Cathéters intravasculaires — Cathéters stériles et non réutilisables —

Partie 8: Cathéters destinés au traitement extracorporel du sang

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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 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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This document was prepared by Technical Committee ISO/TC 84, *Devices for administration of medical products and catheters*.

A list of all parts in the ISO 10555 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.

Intravascular catheters — Sterile and single-use catheters —

Part 8: Catheters for extracorporeal blood treatment

1 Scope

This document specifies general requirements for intravascular catheters, supplied in sterile condition and intended for extracorporeal blood treatments (EBT).

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 10555-1, *Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements*

ISO 10555-3, *Intravascular catheters — Sterile and single-use catheters — Part 3: Central venous catheters*

ISO 10555-5, *Intravascular catheters — Sterile and single-use catheters — Part 5: Over-needle peripheral catheters*

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
catheter for extracorporeal blood treatment
catheter for EBT
tubular device, single or multi-lumen, designed to be inserted into the vascular system for blood purification purposes, such as hemodialysis, hemofiltration, apheresis, and therapeutic plasma exchange

3.2
priming volume
total amount of space available to be filled with solution

3.3
arterial flow direction
blood flow direction from the patient to the extracorporeal blood circuit

3.4
venous flow direction
blood flow direction from the extracorporeal blood circuit to the patient

4 Requirements

4.1 General

Unless otherwise specified in this document, catheters for EBT shall conform to ISO 10555-1. Additionally, catheters for EBT shall conform to ISO 10555-3 and ISO 10555-5, where applicable.

4.2 Blood flowrate - pressure testing

The flowrate versus pressure chart shall be determined for both arterial and venous lumens in accordance with the test method described in Annex A.

4.3 Recirculation rate

For multi-lumen catheters, the percent of blood recirculated from the venous lumen opening back into the arterial lumen opening (forward flow direction) shall be determined. Unless contraindicated, the percent of blood recirculated from the arterial lumen opening back into the venous lumen opening (reverse flow direction) shall also be determined.

NOTE See Annex B for an example test method.

4.4 Mechanical haemolysis testing

Dynamic in vitro mechanical haemolysis testing is required to assess potential blood damage caused by the catheter during treatment as per its intended use. Testing shall assess how much haemolysis (erythrocyte damage resulting in plasma free haemoglobin) occurs when the device is placed in a recirculating blood loop that mimics the pressure and flow conditions of the expected worst-case clinical use of the device.

Testing shall report how the concentration of plasma free haemoglobin increases over time during testing. Due to variations in sample blood used for testing, paired testing with a predicate device is recommended in order to accurately assess haemolysis as well as testing according to standardized methodologies (see e.g. ASTM F1841).

4.5 Colour codes

The colour code of the lumen (e.g. visualized by the colour of the hub or clamp) shall indicate the direction of the blood flow. A red colour code shall indicate arterial flow direction; a blue colour code shall indicate venous flow direction.

4.6 Information to be supplied by the manufacturer

Information supplied by the manufacturer shall conform to ISO 10555-1 and shall also include the following:

a) the flowrates and resulting pressures for each lumen, by provision of the flowrate versus pressure chart, which shall be determined in accordance with Annex A;

   NOTE The clinically relevant unit for blood pressure is mmHg. Therefore, flowrate versus pressure charts with pressures given in mmHg are considered clinically sufficient for the information to be supplied by the manufacturer.

b) for multi-lumen catheter, the priming volume of each lumen based on theoretical analysis;

c) for single-lumen catheter, the priming volume based on theoretical analysis only if applicable (e.g. for products intended to be used for single-needle dialysis);

d) for multi-lumen catheters:

   — the percent recirculation in forward flow direction;

   — unless contraindicated, the percent recirculation in reverse flow direction.