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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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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.

Annex A
(normative)

Test method for blood flowrate – pressure testing

A.1 Principle for the test

The test simulates the catheter blood flow in two directions, arterial flow direction and venous flow direction. The catheter is connected via its hub or proximal end to a real or simulated connector tube, which is connected to a constant-flowrate source, filled with test fluid. The source flowrate is varied incrementally while the pressure is measured via pressure gauge at the source outlet in order to determine the blood flow pressure curve.

NOTE In arterial flow direction, the resulting pressure reading is in negative range, whereas the resulting pressure reading in venous flow direction is in positive range.

A.2 Apparatus

A.2.1 Constant-flowrate source, which supplies the test fluid to the catheter and connector-tube assembly while maintaining the desired flowrate ±10 % throughout the measurement period.

A.2.2 Container for delivering and collecting the test fluid at (37 ± 2) °C.

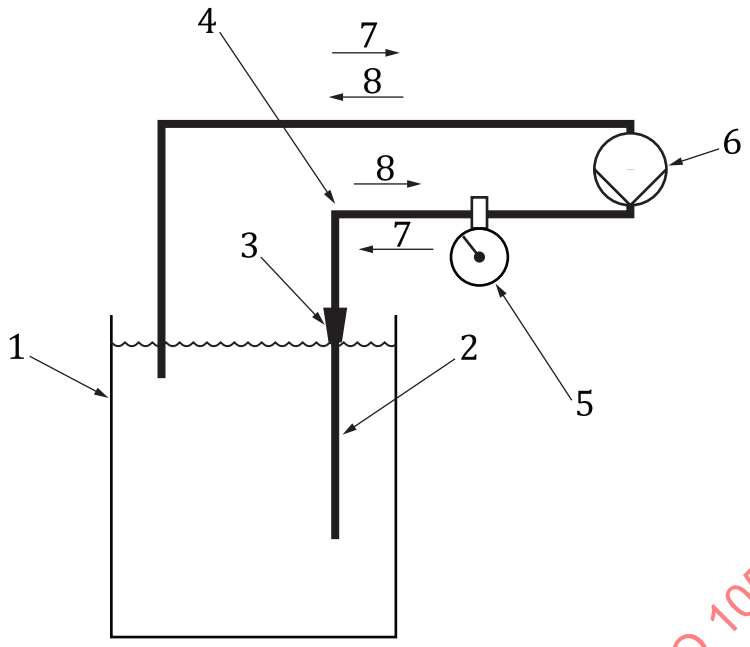
A.2.3 Test fluid, anticoagulated human or bovine plasma with a protein content of (60 ± 5) g/l or anticoagulated whole blood with a haematocrit of (32 ± 3) % and a plasma protein content of (60 ± 5) g/l (see ISO 8637-1). Alternatively, simulated blood with a dynamic viscosity range of 3,2 mPa·s to 3,8 mPa·s at (37 ± 2) °C may be used.

A.2.4 Real or simulated connector tube of clinically relevant internal diameter and length.

A.2.5 Inline pressure transducer inserted between the distal end of the constant-flowrate source and the simulated connector tube.

NOTE 1 A pressure gauge at the constant-flowrate source outlet can be used to measure the resulting pressure; alternatively, source internal pressure-monitoring functions can be used for this same purpose.

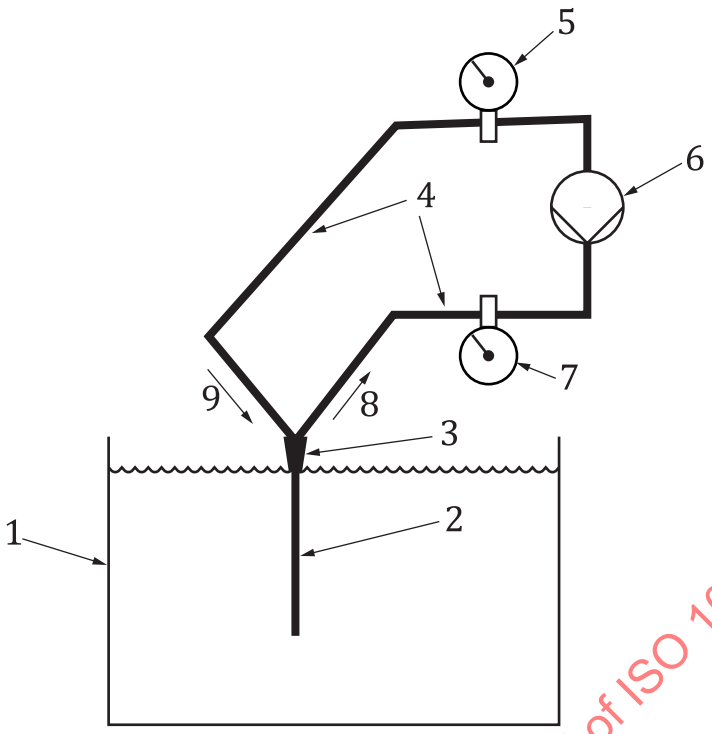
NOTE 2 The general arrangement of the apparatus is shown in Figure A.1 and Figure A.2. The apparatus is not shown in detail, as it can vary in design, complexity and degree of automation.



Key

1 test fluid container
2 catheter under test
3 catheter hub
4 connector/extension tube
5 inline pressure transducer
6 constant-flowrate source
7 venous flow direction
8 arterial flow direction

Figure A.1 — General arrangement of test apparatus for blood flowrate test and resulting pressure for single-lumen catheter



Key

1 test fluid container
2 catheter under test
3 channel junction with extension line
4 connector/extension tube
5 inline pressure transducer venous pressure
6 constant-flowrate source for venous flow direction
7 inline pressure transducer arterial pressure
8 arterial flow direction
9 venous flow direction

Figure A.2 — General arrangement of test apparatus for blood flowrate test and resulting pressure for multi-lumen catheter

A.3 Test procedure

WARNING — It is essential that precautions and safeguards be taken to protect the test operator from the consequences of potential failure of the pressurized system and the resulting escape of fluid under pressure.

A.3.1 Fill the test fluid container, bring the test fluid to (37 ± 2) °C, and maintain this temperature throughout the test.

A.3.2 Attach the real or simulated connector tube to the constant-flowrate source.

A.3.3 Prepare the catheter as indicated in the instructions for use.

A.3.4 Set the system flowrate to the flowrate which is intended to be tested.

A.3.5 Immerse the catheter parts that are intended to be inserted into the body into the test chamber fluid for a minimum of 1 min prior to testing to allow thermal equilibrium.

A.3.6 Purge the system of all air.

A.3.7 Initiate flow through the system based on the intended flow direction.

A.3.8 During the test run, record the maximum pressure at the constant-flowrate source outlet.

A.3.9 Repeat this procedure for a minimum of five flowrates that span the entire range of the blood-flow pressure curve in the information supplied by the manufacturer.

A.4 Test report

The test report shall include at least the following information:

a) identity of the tested catheters;

b) reference to this document (including its year of publication), i.e. ISO 10555-8:2024, Annex A;

c) properties of the test fluid in accordance with the requirements in A.2.3;

d) length (cm) and internal diameter (mm) of the connector tubing;

e) tested flowrates (ml/min) in arterial flow direction;

f) the maximum, minimum, mean and standard deviation of the resulting pressure (Pa and mmHg) achieved at the constant-flowrate source in arterial flow direction for each flowrate test;

g) tested flowrates (ml/min) in venous flow direction;

h) the maximum, minimum, mean and standard deviation of the resulting pressure (Pa and mmHg) achieved at the constant-flowrate source in venous flow direction for each flowrate test;

i) test values in a flowrate versus pressure chart;

j) any deviations from the procedure;

k) the date of the test.

Annex B
(informative)

Test method for determination of recirculation rate

B.1 Principle

An anatomical blood loop model is created by recirculating real or simulated blood through a test-section. The catheter under test is placed into the blood loop test-section and brought to a circulating state using the same test fluid as the anatomical blood loop. The catheter venous flow is titrated with an analytical marker of known concentration (C_v). The concentration of the analytical marker in the catheter arterial flow (C_a) is monitored and used to calculate the recirculation rate from one lumen to the other.

B.2 Apparatus

B.2.1 Test fluid, anticoagulated human or bovine plasma with a protein content of (60 ± 5) g/l or anticoagulated whole blood with a haematocrit of (32 ± 3) % and a plasma protein content of (60 ± 5) g/l (see ISO 8637-1). Alternatively, simulated blood with a dynamic viscosity range of 3,2 mPa·s to 3,8 mPa·s at (37 ± 2) °C may be used.

B.2.2 Analytical marker fluid, readily miscible with the test fluid, and whose concentration can be measured in real-time.

B.2.3 Anatomical blood loop model, consisting of several parts.

B.2.3.1 Recirculation reservoir capable of maintaining the test fluid at (37 ± 2) °C.

B.2.3.2 Pump capable of recirculating the test fluid at 2 l/min ± 10 %.

B.2.3.3 Rigid cylindrical test section 7 cm long × 2 cm diameter.

B.2.3.4 Conical diffuser, placed between the connector tubing and test section with no greater than a 5° included angle of divergence (Figure B.3).

B.2.3.5 Connector tubing to connect the reservoir, pump, and diffuser.

B.2.4 Extracorporeal blood loop model, consisting of several parts.

B.2.4.1 Connector tubing forming a loop between the arterial and the venous ports of the catheter to be tested.

B.2.4.2 Pump capable of circulating the test fluid through the catheter at the desired flowrate, not to exceed 600 ml/min.

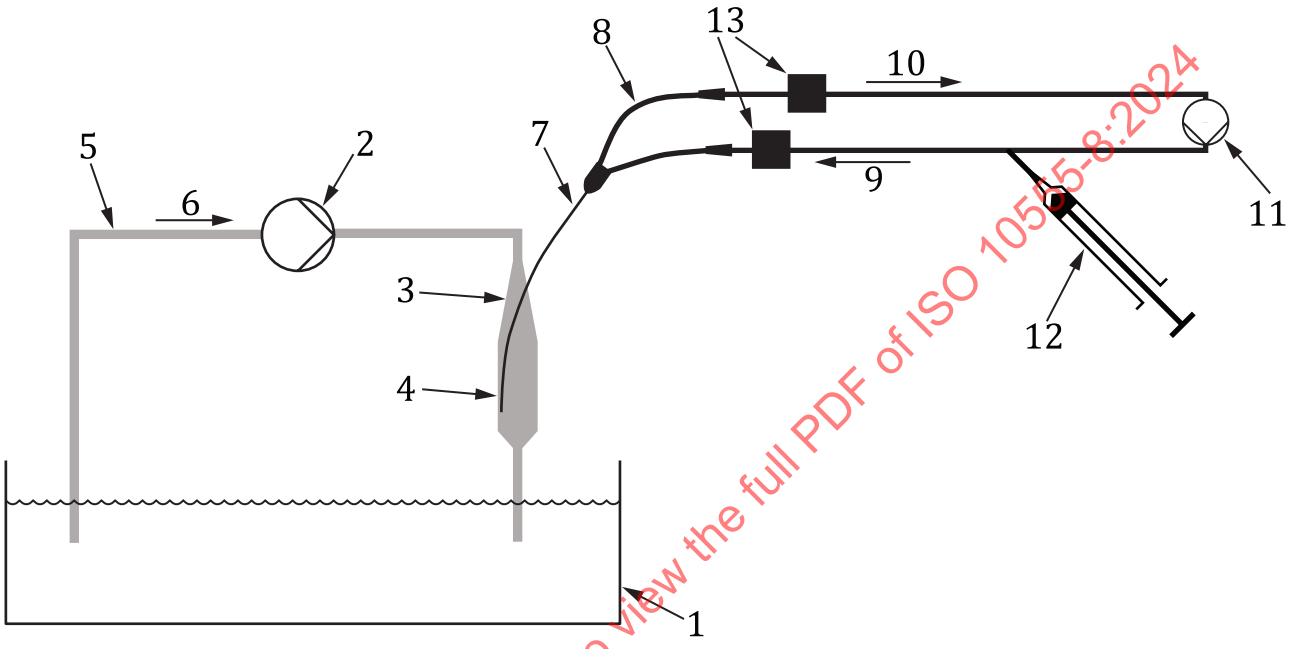
B.2.4.3 Venous reservoir for test fluid (B.2.1) and analytical marker fluid (B.2.2) (Figure B.2).

B.2.4.4 Arterial reservoir for collecting the arterial effluent (Figure B.2).

B.2.4.5 Method of injecting the analytical marker fluid into the venous side of the connector tubing (Figure B.1).

B.2.4.6 Method of measuring the concentration of the analytical marker fluid in the venous (C_v) and arterial (C_a) lumens of the catheter online. Alternatively, a method of measuring the concentration of the analytical marker fluid offline after collection of the arterial effluent from the arterial reservoir.

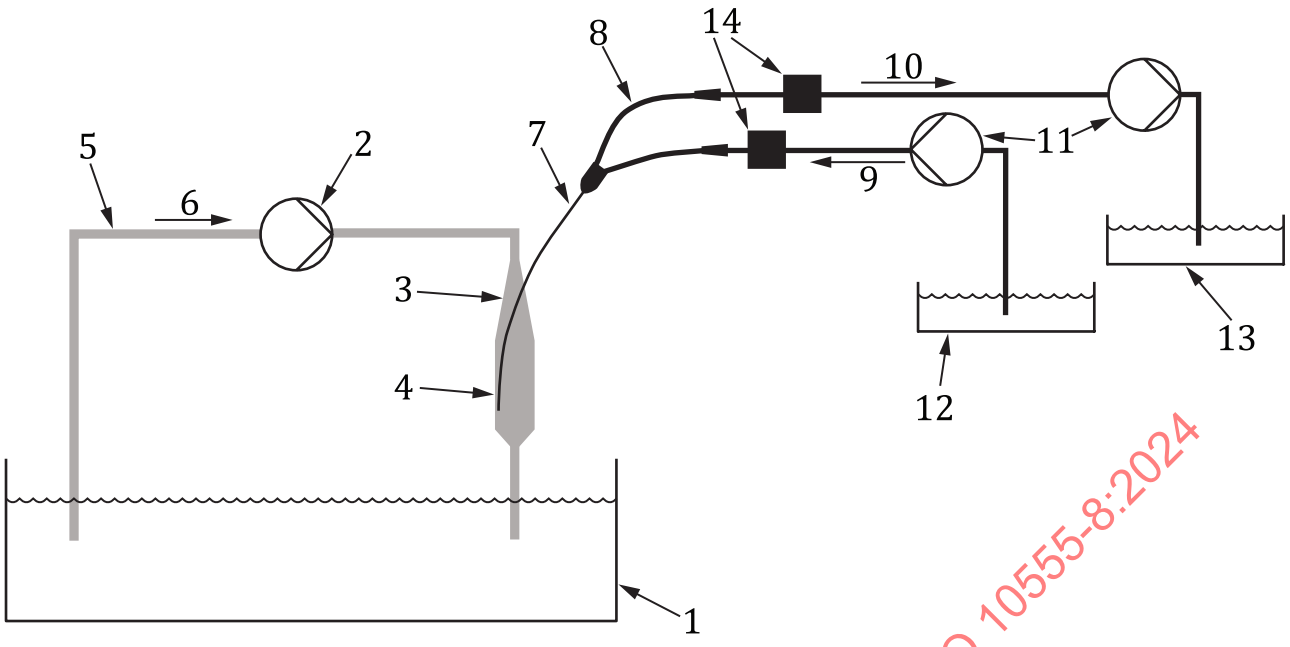
NOTE The general arrangement of the apparatus is shown in Figure B.1. The apparatus is not shown in detail, as it can vary in design, complexity, and degree of automation. For example, Figure B.2 illustrates how the extracorporeal blood loop can be constructed as an open arrangement with a venous reservoir containing the test fluid and analytical marker fluid, and an arterial reservoir which can be used to collect and analyse the arterial effluent.



Key

1 recirculation reservoir (B.2.3.1) containing test fluid (B.2.1)
2 pump for driving the anatomical blood loop model (B.2.3.2)
3 conical diffuser (B.2.3.4)
4 cylindrical test section (B.2.3.3)
5 connector tubing for anatomical blood loop (B.2.3.5)
6 flow direction in the anatomical blood loop
7 catheter shaft/tubing under test
8 catheter extension tubes
9 connector tubing with flow in the venous direction (B.2.4.1)
10 connector tubing with flow in the arterial direction (B.2.4.1)
11 pump to drive the extracorporeal blood loop (B.2.4.2)
12 method of injecting the analytical marker fluid into the venous side of the connector tubing (B.2.4.5)
13 method of measuring the concentration of the analytical marker fluid (B.2.4.6)

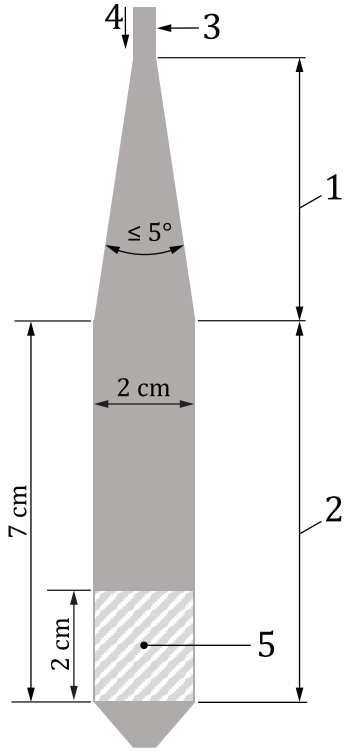
Figure B.1 — General arrangement of test apparatus for assessing recirculation rates



Key

1 recirculation reservoir (B.2.3.1) containing test fluid (B.2.1)
2 pump for driving the anatomical blood loop model (B.2.3.2)
3 conical diffuser (B.2.3.4)
4 cylindrical test section (B.2.3.3)
5 connector tubing for anatomical blood loop (B.2.3.5)
6 flow direction in the anatomical blood loop
7 catheter shaft/tubing under test
8 catheter extension tubes
9 connector tubing with flow in the venous direction (B.2.4.1)
10 connector tubing with flow in the arterial direction (B.2.4.1)
11 pump(s) to drive the extracorporeal blood loop (B.2.4.2)
12 venous reservoir (B.2.4.3) containing test fluid (B.2.1) and analytical marker (B.2.2)
13 arterial reservoir (B.2.4.4) for collecting the arterial effluent
14 method of measuring the concentration of the analytical marker fluid (B.2.4.6)

Figure B.2 — Example of an alternative arrangement of test apparatus for assessing recirculation rates



Key

1 conical diffuser (B.2.3.4)
2 cylindrical test section (B.2.3.3)
3 connector tubing for anatomical blood loop (B.2.3.5)
4 flow direction in the anatomical blood loop
5 tip placement zone

Figure B.3 — Close-up-view of test section

B.3 Test procedure

B.3.1 Assemble the test apparatus by connecting the various tubing, pumps, analysers, and reservoirs as shown in Figure B.1 or Figure B.2, and Figure B.3.

B.3.2 Prepare test fluid as directed in B.2.1.

B.3.3 Prepare the analytical marker fluid of B.2.2 for addition to the venous flow.

B.3.4 Fill the recirculation reservoir of the anatomical blood loop and bring the test fluid to required temperature.

B.3.5 The test fluid in the anatomical blood loop shall be regularly monitored and adjusted to maintain the correct blood properties, simulated blood viscosity, temperature, and to ensure the concentration of analytical marker remains negligible in the recirculation measurement.

B.3.6 Prepare the catheter as indicated in instructions for use, attach to the connector tubing, and install into the cylindrical test section of the apparatus, with the catheter tip located in the downstream 2 cm of the cylindrical test section (see Figure B.3).

B.3.7 Purge both loops of all air and bring both loops to a circulating state.