

INTERNATIONAL STANDARD

ISO
10555-3

First edition
1996-06-15

Sterile, single-use intravascular catheters — **Part 3:** Central venous catheters

Cathéters intravasculaires stériles, non réutilisables —
Partie 3: Cathéters centraux veineux



Reference number
ISO 10555-3:1996(E)

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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 10555-3 was prepared by Technical Committee ISO/TC 84, *Medical devices for injections*, Subcommittee SC 1, *Syringes, needles and intravascular catheters for single use*.

ISO 10555 consists of the following parts, under the general title *Sterile, single-use intravascular catheters*:

- Part 1: *General requirements*
- Part 2: *Angiographic catheters*
- Part 3: *Central venous catheters*
- Part 4: *Balloon dilatation catheters*
- Part 5: *Over-needle peripheral catheters*

Annex A forms an integral part of this part of ISO 10555. Annex B is for information only.

© ISO 1996

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

Sterile, single-use intravascular catheters —

Part 3: Central venous catheters

1 Scope

This part of ISO 10555 specifies requirements for central venous catheters supplied in the sterile condition, and intended for single use.

NOTE 1 Attention is drawn to ISO 11070, which specifies requirements for accessory devices for use with intravascular catheters.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 10555. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 10555 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 594-1:1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements.*

ISO 10555-1:1995, *Sterile, single-use intravascular catheters — Part 1: General requirements.*

3 Definitions

For the purposes of this part of ISO 10555, the definitions given in ISO 10555-1 and the following definition apply.

3.1 central venous catheter: Intravascular catheter, single- or multilumen, designed for introduction into, or withdrawal of liquids from, the central venous system and/or for pressure or other measurements.

NOTE 2 The catheter may have a fixation system which is part of the device.

4 Requirements

4.1 General

Catheters shall comply with ISO 10555-1, except for the force at break (see ISO 10555-1:1995, subclause 4.5), for which the requirements of subclause 4.7 of this part of ISO 10555 shall apply.

4.2 Radio-detectability

The catheter shall be radio-detectable.

NOTE 3 At the time of publication of this part of ISO 10555, there is no acceptable, validated test method to determine radio-detectability. An approved test method for producing a value of radio-detectability will be established. Until that time, a manufacturer may label his product "radio-opaque" provided he can support this claim by demonstrating that he has an appropriate method for showing radio-opacity.

4.3 Tip configuration

In order to minimize trauma to vessels during use, the tip of the distal end should be smooth, rounded, tapered or similarly finished.

4.4 Distance markings

If the catheter is provided with distance markings, the marking system shall indicate distance from the distal end. From the first mark, the distance between marks shall not exceed 5 cm.

NOTE 4 It is recommended that the distance marks be 1 cm apart on that portion of the catheter likely to be of importance to the user in positioning the catheter and monitoring catheter migration.

4.5 Lumen markings

For multilumen catheters, identification of each lumen shall be apparent to the user.

4.6 Flowrate

When tested in accordance with annex A, the flowrate for each lumen shall be between 80 % and 125 % of that stated by the manufacturer for catheters of nominal outside diameter less than 1,0 mm or between 90 % and 115 % of that stated by the manufacturer for catheters of nominal outside diameter 1,0 mm or greater.

4.7 Force at break

4.7.1 For catheters having a tip of softer durometer material or of different construction to the shaft and not exceeding 20 mm in length, the minimum force at break of the tip shall be as given in table 1 when tested in accordance with the method given in annex B of ISO 10555-1:1995.

The minimum force at break of all other parts of such catheters shall comply with ISO 10555-1:1995, subclause 4.5.

4.7.2 The minimum force at break of all parts of catheters other than those to which 4.7.1 applies shall comply with ISO 10555-1:1995, subclause 4.5.

Table 1 — Minimum force at break of soft tips of length not exceeding 20 mm

Smallest outside diameter of catheter body mm	Minimum force at break N
$\geq 0,550$ and $< 0,75$	3
$\geq 0,75$ and $< 1,85$	4
$\geq 1,85$	5

4.8 Information to be supplied by the manufacturer

Information supplied by the manufacturer shall comply with ISO 10555-1 and shall also contain the following:

- if the catheter is provided with distance markings, a description of the marking system;
- flowrate for each lumen;
- maximum guidewire diameter, where applicable;
- if applicable, a warning against attempting to withdraw the catheter back through the needle.

NOTE 5 Units of measurement systems other than those specified in this part of ISO 10555 may additionally be used.

Annex A (normative)

Determination of flowrate through the catheter

A.1 Principle

Water is allowed to flow through the catheter and the amount of flow is measured either volumetrically or gravimetrically.

A.2 Reagent

Distilled or deionized water.

A.3 Apparatus

A.3.1 Constant-level tank, fitted with a delivery tube and a male 6 % (Luer) taper fitting complying with ISO 594-1, capable, when no test catheter is attached, of providing a flowrate of (525 ± 25) ml/min, and having a hydrostatic head height of $(1\,000 \pm 5)$ mm.

An example of a suitable apparatus is shown in figure A.1.

A.3.2 Equipment for collecting and determining the mass or volume of the catheter efflux to an accuracy of ± 1 %.

A.3.3 Timer, for measuring collection time.

A.4 Test procedure

A.4.1 Supply the constant-level tank (A.3.1) with water at (22 ± 2) °C. Fit the catheter to be tested to the male 6 % (Luer) taper fitting.

A.4.2 Start the water flowing through the catheter. Collect the efflux for a measured period of time (not less than 30 s) in a suitable vessel and determine its volume by means of a measuring cylinder or by weighing, assuming that the density of water equals $1\,000$ kg/m³.

A.4.3 Perform three determinations on each catheter lumen.

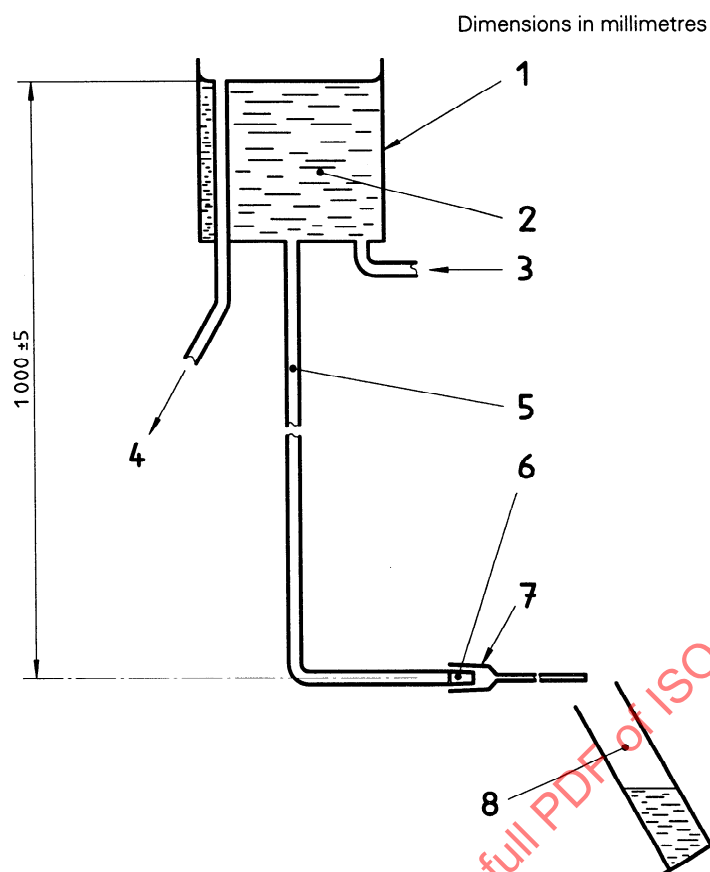
A.5 Expression of results

Calculate the arithmetic average of the three determinations and express it as water flowrate through the catheter, in millilitres per minute. Round the calculated average water flowrate to the nearest whole number of millilitres.

A.6 Test report

The test report shall include the following information:

- identity of the catheter;
- average flowrate, expressed in millilitres per minute, for each lumen.

**Key**

- 1 Constant-level tank
- 2 Distilled or deionized water
- 3 Inlet
- 4 Overflow
- 5 Delivery tube
- 6 Male 6 % (Luer) taper fitting
- 7 Catheter under test
- 8 Collecting/measuring vessel

Figure A.1 — Example of apparatus for determination of flowrate of water through catheter