



**International
Standard**

ISO 7199

**Cardiovascular implants and
artificial organs — Blood-gas
exchangers (oxygenators)**

*Implants cardiovasculaires et organes artificiels — Échangeurs
gaz/sang (oxygénateurs)*

**Fourth edition
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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.

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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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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 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*, 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 fourth edition cancels and replaces the third edition (ISO 7199:2016), which has been technically revised. It also incorporates the Amendment ISO 7199:2016/Amd.1:2020.

The main changes are as follows:

- circular definitions have been corrected for platelet reduction (3.10), plasma free haemoglobin (3.11) and white blood cell reduction (3.12);
- the definition of priming volume (3.18) has been added;
- the sampling time point of 5 min has been deleted in Table 2.

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.

Introduction

This document is intended to ensure that devices designed to affect the exchange of gases in support of, or as a substitution for, the normal respiratory function of the lungs have been adequately tested for both their safety and function, and that extracorporeal device characteristics are appropriately disclosed when labelling the device.

This document therefore contains procedures to be used for the evaluation of extracorporeal blood-gas exchangers (oxygenators). Type test procedures to determine the gas transfer, blood cell damage and heat exchanger performance are described, although limits for these characteristics are not specified. Ready identification of the performance characteristics should, however, assist the user in the selection of an oxygenator that suits the needs of the patient.

This document also includes minimum reporting requirements that allow the user to compare performance characteristics of oxygenators of different designs in a standard way.

This document makes reference to other International Standards in which methods for the determination of characteristics common to medical devices can be found.

No provisions have been made for the quantification of microbubble generation or for the non-formed elements of bovine blood because there currently is no consensus regarding satisfactorily reproducible test methods.

Requirements for animal and clinical studies have not been included in this document.

This document contains only those requirements that are specific to oxygenators. Since non-toxicity is anticipated to be the subject of a future horizontal/level 1 standard, this document does not cover non-toxicity.

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Cardiovascular implants and artificial organs — Blood-gas exchangers (oxygenators)

1 Scope

This document specifies requirements for sterile, single-use, extracorporeal blood-gas exchangers (oxygenators) intended for the supply of oxygen to, and the removal of carbon dioxide from, human blood, during cardiopulmonary bypass (CPB) for up to 6 h, extracorporeal lung assist [ECLA with veno-venous (VV), veno-arterial (VA) or veno-arterial-venous (VAV) cannulation strategies], cardiopulmonary support (CPS), extracorporeal life support (ECLS with VA cannulation strategy), extracorporeal carbon dioxide removal (ECCO₂R), and other extracorporeal circulation techniques requiring blood-gas exchange.

This document also applies to heat exchangers and arterial filters that are integral parts of the oxygenator.

This document also applies to external equipment unique to the use of the oxygenator.

This document does not apply to

- implanted oxygenators,
- liquid oxygenators,
- extracorporeal circuits (blood tubing),
- separate heat exchangers,
- separate ancillary devices, and
- separate arterial line filters.

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

ISO 10993-11, *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

ISO 17665, *Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices*

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

blood-gas exchanger oxygenator

extracorporeal device designed to supplement, or be a substitute for, the respiratory function of the lungs

3.2

blood pathway

portion of the *oxygenator* (3.1) containing blood during intended clinical use

3.3

gas pathway

portion of the *oxygenator* (3.1) containing the ventilation gas during intended clinical use

3.4

heat exchanger

component that is intended to control the temperature of the circulating blood or priming solution

3.5

heat exchanger performance factor

R

ratio of the difference between the temperature of blood at the outlet of the *oxygenator* (3.1) and the temperature of blood at the inlet of the *oxygenator* to the difference between the temperature of the water at the inlet of the *heat exchanger* (3.4) and the temperature of blood at the inlet of the *oxygenator*

3.6

integral arterial filter

component that is intended to filter particles such as blood clots, debris and gas emboli from the blood

3.7

filtration efficiency

ability of the filter to remove particles from the simulated blood suspension test fluid

Note 1 to entry: Filtration efficiency is expressed as a percentage.

3.8

integral part

part that is connected to the *oxygenator* (3.1) and cannot normally be separated by the user

3.9

operating variable

setting of controls that affects the function of the device

3.10

platelet reduction

decrease in platelet count in a circuit incorporating an *oxygenator* (3.1)

Note 1 to entry: Platelet reduction is expressed as a percentage.

3.11

plasma free haemoglobin

haemoglobin that is released from the red blood cells to the plasma

3.11.1

normalized index of haemolysis

NIH

mass of *plasma free haemoglobin* (3.11) released after pumping 100 l of blood

$$\text{NIH} = \Delta f_{\text{Hb}} \cdot V \cdot \frac{100 - \text{Hct}}{100} \cdot \frac{100}{Q \cdot t}$$

where

Δf_{Hb} is the increase of plasma free haemoglobin concentration over the sampling time interval, in g/l;

V is the circuit volume, in l;

Q is the flow rate, in l/min;

Hct is the haematocrit, in %;

t is the sampling time interval, in min

Note 1 to entry: The normalized index of haemolysis is expressed in grams per hectolitre.

3.12

white blood cell reduction

decrease in white blood cell count in a circuit incorporating an *oxygenator* (3.1)

Note 1 to entry: White blood cell reduction is expressed as a percentage.

3.13

residual blood volume

difference between the priming volume of the unit and the blood volume that can be extracted

3.14

blood analogue

test solution which simulates certain blood characteristics relevant for testing, such as viscosity and salinity

3.15

subject device

device under test

3.16

comparator device

device similar to the *subject device* (3.15) that is a legally marketed device, recognized-to-be-safe and is used for the same intended clinical use

3.17

worst-case condition

operating variable (3.9) within those specified by the manufacturer for intended clinical use which represents the supposed worst-case device operation for the respective test

3.18

priming volume

amount of fluid needed to fill the blood path of the device

4 Requirements

4.1 Biological characteristics

4.1.1 Sterility and non-pyrogenicity

The blood pathway shall be sterile and non-pyrogenic.

Compliance shall be verified in accordance with [5.2.1](#).

4.1.2 Biocompatibility

All parts of the blood pathway shall be biocompatible with respect to their intended use.

Compliance shall be verified in accordance with [5.2.2](#).

4.2 Physical characteristics

4.2.1 Blood pathway integrity

When tested in accordance with [5.3.1](#), the blood pathway shall not leak.

4.2.2 Heat exchanger fluid pathway integrity

When tested in accordance with [5.3.2](#), the heat exchanger fluid pathway shall not leak.

4.2.3 Blood volumes

When tested in accordance with [5.3.3](#), the volume of the blood pathway shall be within the tolerances specified by the manufacturer (see [6.3](#)).

4.2.4 Connectors

Connectors for connection to the blood pathway shall, when tested in accordance with [5.3.4](#), allow a secure connection.

When tested in accordance with [5.3.4](#), the gas inlet connection to the gas pathway shall not separate.

NOTE 1 Connectors of a type that allows connection of tubes with an inner diameter of 4,8 mm, 6,3 mm, 9,5 mm or 12,7 mm, a type that complies with ISO 8637-1:2017, Figure 1, or a type that complies with ISO 80369-7:2021 have been found satisfactory.

NOTE 2 Connectors with dimensions as given in [Annex A](#) and fitting to functional gauges and reference steel fittings is a way to comply with this requirement.

Performance testing of the connectors shall be performed in accordance with ISO 80369-7:2021, Clause 6. The reference fittings given in [Annex A](#) can be used in the performance testing of the connectors.

Connectors for the heat exchanger fluid pathway shall be capable of being connected to female fast couplings.

NOTE 3 Connectors corresponding to ISO 8637-1:2017, Figure 2 are considered as one way to comply with this requirement.

4.3 Performance characteristics

4.3.1 Oxygen and carbon dioxide transfer rates

When determined in accordance with [5.4.1](#), the oxygen and carbon dioxide transfer rates shall be within the range of values specified by the manufacturer (see [6.3](#)).

4.3.2 Heat exchanger performance factor

When determined in accordance with 5.4.2, the heat exchanger performance factors shall be within the range of values specified by the manufacturer (see 6.3).

4.3.3 Integral arterial filtration efficiency

When tested in accordance with 5.4.5, filtration efficiency of any individual device should be at least 80 % when tested with particles that are 20 % larger than the nominal pore size of the filter.

4.3.4 Integral arterial filter flow rate capacity

When tested in accordance with 5.4.6, test results shall demonstrate the flow rate and pressure limitation(s) to ensure safe and effective performance, as specified by the manufacturer.

4.3.5 Integral arterial filter air handling capability

When tested in accordance with 5.4.7, test results shall demonstrate the air-handling capability, as specified by the manufacturer.

4.3.6 Blood cell damage

4.3.6.1 Plasma free haemoglobin

When determined in accordance with 5.4.3, the increased concentration of plasma free haemoglobin shall be within the range of values specified by the manufacturer.

The haemolysis results shall be reported in mg/dl and the NIH shall be given.

4.3.6.2 Platelet reduction and white blood cell reduction

When determined in accordance with 5.4.3, the percentage reduction of platelets and the percentage reduction of white blood cells shall be within the range of values specified by the manufacturer.

4.3.7 Time-dependent performance changes

When determined in accordance with 5.4.1, the oxygen and carbon dioxide transfer rates shall remain consistent within the range of values over the duration of the testing specified by the manufacturer.

4.3.8 Shelf life

When tested in accordance with 5.4.4, the test results should demonstrate the rated shelf life, as specified by the manufacturer.

5 Tests and measurements to determine compliance with this document

5.1 General

5.1.1 Tests and measurements shall be performed with the subject device prepared in accordance with the manufacturer's instructions for intended clinical use. Performing additional pre-conditioning can be required such as sterilization cycling, environmental exposure, shipping exposure and aging.

5.1.2 Operating variables shall be those specified by the manufacturer for intended clinical use, unless otherwise specified.

5.1.3 Unless otherwise stated, the temperature of test liquids shall be $(37 \pm 1) ^\circ\text{C}$.

5.1.4 If the relationship between variables is nonlinear, sufficient determinations shall be made to permit valid interpolation between data points.

5.1.5 The test or measurement procedures shall be regarded as reference procedures. Other procedures can be accepted, provided that the alternative procedure has been shown to be of comparable precision and reproducibility.

5.2 Biological characteristics

5.2.1 Sterility and non-pyrogenicity

Compliance shall be verified by inspection of the manufacturer's documentation on sterilization and pyrogen testing, in accordance with ISO 17665-1, ISO 11135, ISO 11137-1 and ISO 10993-11, as applicable.

5.2.2 Biocompatibility

Compliance shall be verified by test or by inspection of the manufacturer's documentation on biocompatibility for the finished device, in accordance with ISO 10993-1.

5.3 Physical characteristics

5.3.1 Blood pathway integrity

5.3.1.1 Test liquid

The test liquid shall be water.

5.3.1.2 Procedure

Place the subject device in an appropriate test circuit. Subject the blood pathway of the device to a pressure that is $1,5\times$ the maximum pressure specified by the manufacturer for intended clinical use. If no maximum pressure is specified, the test shall be performed at 152 kPa. Maintain this pressure for 6 h or as long as it is specified by the manufacturer for clinical use. Visually inspect the device for leakage of water.

For blood gas exchangers with an intended use in pulsatile mode, perform a blood path integrity test under dynamic pulsatile worst-case conditions (e.g. frequency, flow rate, pressure) in addition to non-pulsatile testing.

5.3.2 Heat exchanger water pathway integrity

5.3.2.1 Test liquid

The test liquid shall be water.

5.3.2.2 Procedure

Place the device under test in an appropriate test circuit. Subject the heat exchanger fluid pathway to a pressure $1,5\times$ that specified by the manufacturer for intended clinical use. If no maximum pressure is specified, the test shall be performed at 350 kPa. Maintain this pressure for 6 h or as long as is specified by the manufacturer for intended clinical use and visually inspect the device for leakage of water.

5.3.3 Blood volumes

5.3.3.1 Test liquid

The test liquid shall be anticoagulated whole blood. To determine the priming volume, water or saline can be used.

5.3.3.2 Procedure

The volume of the blood pathway shall be determined. If the operating variables (e.g. pressure) can affect the priming volume, the evaluation should be performed over the range specified by the manufacturer for intended clinical use.

Residual blood volume is determined by holding the unit in its most advantageous drainage position for 20 s past the time that air first appears at the port being used for drainage until no remaining volume is noted in the device.

5.3.4 Connectors

The connection shall be made in accordance with the manufacturer's instructions for use.

The connection shall withstand a pull force of 15 N for 15 s without separating.

5.4 Performance characteristics

5.4.1 Oxygen and carbon dioxide transfer rates

5.4.1.1 Test media

The test liquid for the blood pathway shall be anticoagulated whole blood. The test medium for the gas pathway shall be gas of known oxygen, nitrogen and carbon dioxide concentrations.

5.4.1.2 Procedure

5.4.1.2.1 General

Place the subject device in an appropriate test circuit. Perform tests using the following blood inlet conditions during the determination of oxygen and carbon dioxide transfer rates:

- oxyhaemoglobin percentage: $(65 \pm 5) \%$;
- haemoglobin: $(120 \pm 10) \text{ g/l}$;
- base: $(0 \pm 5) \text{ mmol/l}$;
- partial pressure of carbon dioxide in blood, p_{CO_2} : $(6,0 \pm 0,7) \text{ kPa}$.

Oxygen and carbon dioxide transfer rates shall be determined over the manufacturer's specified range of operating variables (see [6.3](#)).

Between each set of measurements, the blood flow shall be kept at the maximum specified by the manufacturer for intended clinical use (see [6.3](#)).

The oxygen and carbon dioxide transfer rates shall be determined at the initiation of the test. For dependent determinations, measurements shall be performed at the beginning of the test, and then at 90 min, 180 min, 270 min and 360 min after the start of the test.

In vitro tests as well as tests using an appropriate animal model, for longer than 6 h, are acceptable.

Data need not be collected at the precise conditions specified. Approximations obtained by reasonable interpolation are acceptable.

5.4.2 Heat exchanger performance factor

5.4.2.1 Test liquid

The test liquid for the blood pathway shall be anticoagulated whole blood or water.

5.4.2.2 Procedure

Place the device under test in an appropriate test circuit. Perform the test in vitro under the following conditions:

- blood inlet temperature, $T_{in,blood}$: (30 ± 1) °C;
- water inlet temperature, $T_{in,water}$: (40 ± 1) °C.

The determination of heat exchanger performance factors shall be made over the manufacturer's specified range of operating variables (see [6.3](#)).

5.4.2.3 Formula

The heat exchanger performance factor is given by the following formula:

$$R = \frac{T_{out,blood} - T_{in,blood}}{T_{in,water} - T_{in,blood}}$$

where

$T_{out,blood}$ is the temperature of the blood at the outlet of the oxygenator, in °C;

$T_{in,blood}$ is the temperature of the blood at the inlet of the oxygenator, in °C;

$T_{in,water}$ is the temperature of the water at the inlet of the heat exchanger, in °C.

5.4.3 Blood cell damage

5.4.3.1 Test media

The test liquid for the blood pathway shall be anticoagulated whole blood. The test medium for the gas pathway shall be gas of suitable oxygen, nitrogen and carbon dioxide concentrations.

5.4.3.2 Procedure

The worst-case conditions for blood cell damage shall be identified for both non-pulsatile and pulsatile mode (if applicable). Justify the choice, taking into account: pressure differential, gas flow rate, blood flow rate, amplitude and frequency as per the operational ranges specified by the manufacturer or based on risk assessment. Blood cell damage tests shall be performed under these identified worst-case conditions. Two sets of appropriate, identical circuit components, including a pump, connecting tubing, a reservoir (as specified by the manufacturer and of suitable size relative to the device under test) and a heat exchanger, shall be assembled. The device under test shall be placed in one of the circuits. A comparator device shall be placed in the second test circuit. Priming and debubbling of the circuits by recirculating with an appropriate solution is recommended before adding blood.

The blood pathway test-liquid volumes shall, at the initiation of the test, be within 3 % of each other. The total circuit volume should be chosen to optimize test sensitivity and system noise, and shall not exceed 2 l without appropriate justification. All changes in circuit volume during the test shall be documented (e.g. sampling volume and extra fluid added). Perform the test in vitro using the conditions given in [Table 1](#).

A sufficient number of paired tests (e.g. usually 5) should be performed to support a paired statistical analysis of the test results (haemolysis, white blood cells, and platelets) between the subject and the comparator device. The comparator device should be tested under the same conditions using the same blood pool. The test duration shall be 6 h.

The sampling schedule shall be in accordance with [Table 2](#). More frequent sampling times are optional.

5.4.4 Shelf life

Using a validated method, aging should be performed on final, finished, sterilized devices in primary packaging in order to determine nominal shelf life.

5.4.5 Filtration efficiency

5.4.5.1 Test liquid

The test liquid shall be a glycerin solution or water. The test liquid shall contain 350 to 5 000 particles per millilitre that are 15 % to 25 % larger than the nominal pore size of the filter.

5.4.5.2 Procedure

Pass 500 ml of the test liquid at room temperature (20 °C to 22 °C) through the device at a flow rate of no less than 100 ml/min and a pressure not exceeding 152 kPa [22 pounds per square inch (psi)] gauge.

Determine the prefiltration and post-filtration mean number of particles. The test shall be performed at the manufacturer's recommended flow rates.

Calculate the filtration efficiency, using the readings from the size range of the test particles used for each test sample, by subtracting the post-filtration mean number of particles from the pre-filtration mean, dividing the quotient by the pre-filtration mean number of particles and multiplying by 100 to obtain a percentage.

5.4.6 Integral arterial filter flow rate

5.4.6.1 Test liquid

The test liquid shall be anticoagulated whole blood or blood analogue.

5.4.6.2 Procedure

Place the device under test in an appropriate test circuit. Set the flow rate at the maximum rated flow and monitor the inlet and outlet pressures across the device for 6 h. Measure the flow rate using a calibrated flowmeter. Note any pressure changes during the test.

If anticoagulated whole blood is used, repeat the test if formed elements or proteinaceous aggregates affect the pressure results.

5.4.7 Air-handling capability of integral arterial filter

5.4.7.1 Test liquid

The test liquid shall be anticoagulated whole blood with a haemoglobin content of (12 ± 1) g/dl.

5.4.7.2 Procedure

Use filter vent tubing as specified in the manufacturer's instructions for use. The length and internal diameter of the vent tubing shall be specified. The back pressure at the maximum test flow shall be $26,6 \text{ kPa (3,9 psi)} \pm 5 \%$.

Use a bubble eliminator to measure any air downstream of the integral filter accumulated over a period of 5 min from bolus injection. At flow rates of 33 %, 67 % and 100 % of the specified maximum rated flow rate, a bolus of 30 ml of room air for adult oxygenators (for paediatric or infant oxygenators with a maximum flow rate of less than 500 ml/min the bolus shall be 2,5 ml and for maximum flow rates higher than 500 ml/min the bolus shall be increased by 2,5 ml for every 500 ml/min maximum flow rate; the maximum bolus shall be 10 ml) shall be injected as a single bolus. Indication of the air bolus injection point in the test circuit, rate of injection and type of pump utilized to circulate test liquid should be provided in the test protocol.

For blood gas exchangers with an intended use in pulsatile mode, perform the test described in this subclause under dynamic pulsatile worst-case conditions (e.g. frequency, flow rate, pressure) in addition to non-pulsatile testing.

5.4.7.3 Results

The results shall be reported as the percentage efficiency of gross air removal.

Table 1 — Conditions for in vitro testing of blood cell damage

Item	Level	Maximum variation
Blood flow rate	Identified and justified worst-case conditions specified by the manufacturer for intended clinical use (see 6.3)	±5 %
Gas flow rate	Adequate to maintain the blood gas parameter as required	
p_{CO_2} ^a	5,3 kPa	±0,7 kPa
Base	0 ^b	±5 mmol/l
Blood glucose	10 mmol/l	±5 mmol/l
Haemoglobin	12 g/dl	±1 g/dl

^a p_{CO_2} values achieved 30 min after the start of the test are acceptable.
^b "0" refers to 24 mmol/l bicarbonate (HCO₃⁻).

Table 2 — Sampling schedule

Parameter	Baseline ^a (0 min)	Time after initiation of test min				
		30	90	180	270	360
Plasma free haemoglobin	X	X	X	X	X	X
White blood cell	X	X	X	X	X	X
Platelets	X	X	X	X	X	X
Blood gas values (p_{CO_2} , p_{O_2} , pH, base)	X	X		X		X
Haemoglobin/haematocrit	X	X		X		X
Glucose	X					
Activated clotting time	X			X		X
Temperature	X	X	X	X	X	X
Flow rates	X	X	X	X	X	X
Pressure (inflow and outflow)	X	X	X	X	X	X
Circuit volume changes	X	X	X	X	X	X

^a The baseline is defined as the blood after it has been thoroughly mixed in the flow loop at the start of the test.

6 Information supplied by the manufacturer

6.1 Information on the oxygenator

The following information shall be given on the oxygenator:

- a) the manufacturer's identification;
- b) the batch, lot or serial number designation;
- c) the model designation;
- d) the direction of the flow of either blood or gas or water, or all, if necessary.

6.2 Information on the packaging

6.2.1 Unit container

The following information shall be visible through or given on the unit container:

- a) the manufacturer's name, address and, if available, website and email address;
- b) a description of contents;
- c) the model designation;
- d) a statement on its sterility and non-pyrogenicity;
- e) the expiry date;
- f) the batch, lot or serial number designation;
- g) the words "Read instructions before use."; the symbol shown in [Figure 1](#) may be added before these words;



Figure 1 — ISO 7010-W001

- h) any special handling or storage conditions;
- i) a statement on single use; the symbol shown in [Figure 2](#) may be used.



Figure 2 — ISO 7010-1051

6.2.2 Shipping container

The following information shall appear on the shipping container:

- a) the manufacturer's name and address;

- b) a description of contents, including number of units;
- c) the model designation;
- d) a statement on sterility and non-pyrogenicity;
- e) the expiry date;
- f) any special handling, storage or unpacking instructions.

6.3 Information in the accompanying documents

Each shipping container shall contain an “instructions for use” leaflet with the following information:

- a) the manufacturer's address and telephone or telefax number;
- b) the model designation;
- c) the required ancillary equipment;
- d) the instructions on necessary, special or unique procedures, as applicable;
- e) the directions for placing the oxygenator in a support or operational fixture;
- f) the placement, type and securing of tubing connections;
- g) the location and purpose of additional entry or exit ports;
- h) a heat exchanger priming and operation;
- i) heat exchanger materials and compatibility with heater-cooler device fluids (e.g. water/H₂O₂, non-water-based fluids);
- j) the priming procedure;
- k) the direction of blood, gas and water flows;
- l) the general operating procedures for normal use;
- m) the maximum intended duration of use;
- n) a recommended procedure for intraoperative replacement of an oxygenator;
- o) the maximum and minimum recommended blood flow rates;
- p) the maximum and minimum operating volumes of the blood pathway, including any integral reservoir;
- q) the maximum and minimum specified gas flow rates;
- r) the heat exchanger performance factors;
- s) the air-handling capability;
- t) the residual blood volume;
- u) the oxygen and carbon dioxide transfer rates;
- v) the pressure limitations for blood, water and gas pathways;
- w) additionally, for ECLS indications:
 - 1) a list of critical clinical signals or observations that suggest oxygenator exchange is necessary regardless of the time the device has been in use as a warning or caution statement;

- 2) a recommended warning in order to adequately advise device users regarding the summary of supporting test data:

WARNING — Use of the [NAME OF THE DEVICE] beyond the duration established by the available in vitro, in vivo and clinical data, has not been demonstrated. Please refer to 6.3 v) 3) for a summary of bench data (animal, and clinical data available upon request), as well as 6.3 v) 1) for the possible clinical observations that can necessitate or predict the need for device replacement/exchange throughout the duration of use for this device.

- 3) a summary of the bench data;
- x) a statement that the following are available upon request:
- 1) the sterilization method;
 - 2) a list of materials of the blood pathway;
 - 3) data on plasma leakage across any semi-permeable membrane, if applicable;
 - 4) the blood pathway pressure drop at the range of blood flow rates specified by the manufacturer for intended clinical use;
 - 5) the gas pathway pressure drop at the maximum blood and gas flow rates specified by the manufacturer for intended use;
 - 6) the data related to blood cell damage;
 - 7) the data on particle release from the oxygenator according to the manufacturer's quality control management system;
 - 8) the relevant tolerances for data presented;
 - 9) a summary of animal and clinical data, as applicable, for ECLS indications.

6.4 Information in the accompanying documents in a prominent form

The following information shall be given, in prominent form, in the accompanying documents:

- a) pressure limitations;
- b) flow rate limitations;
- c) blood level limitations;
- d) other device limitations (e.g. pulsatility limitations).

7 Packaging

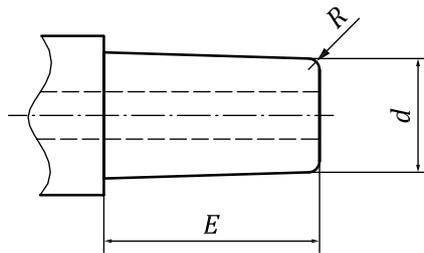
Packaging shall comply with the appropriate requirements of ISO 11607-1 and ISO 11607-2.

Annex A
(informative)

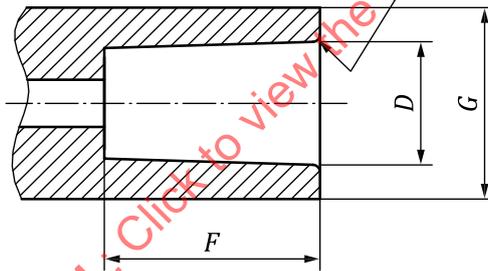
Examples of connectors

A.1 Luer slip fittings

Figures A.1 and A.2 depict Luer slip fittings. For corresponding dimensions, see Table A.1.



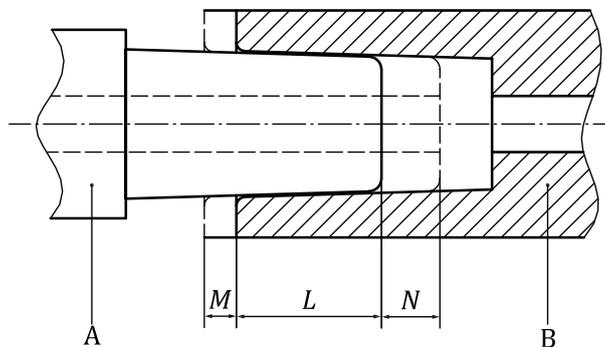
a) Male 6 % (Luer) conical fitting (“male fitting”)



b) Female 6 % (Luer) conical fitting (“female fitting”)

NOTE See Key and dimensions given in Table A.1.

Figure A.1 — Typical 6 % (Luer) conical fittings



NOTE See Key and dimensions given in Table A.1.

Figure A.2 — Typical assembly of 6 % (Luer) conical fittings

Table A.1 — Dimensions of 6 % (Luer) conical fittings

Reference	Designation	Dimensions for		
		Rigid material mm	Semi-rigid material mm	
A	Male fitting	NA	NA	
B	Female fitting	NA	NA	
Basic dimensions	d_{\min}	Minimum diameter of the end of the male conical fitting (reference diameter)	3,925	3,925
	d_{\max}	Maximum diameter at the end of the male conical fitting	3,990	4,027
	D_{\min}	Minimum diameter at the opening of the female conical fitting	4,270	4,270
	D_{\max}	Maximum diameter at the opening of the female conical fitting	4,315	4,315
	E	Minimum length of the male conical fitting	7,500	7,500
	F	Minimum depth of the female conical fitting	7,500	7,500
	G	Maximum outside diameter of female conical fitting	6,730	6,730
Other dimensions	L^a	Minimum length of engagement	4,665	4,050
	M^a	Tolerance for length of engagement of the female conical fitting	0,750	0,750
	N^a	Tolerance for length of engagement of the male conical fitting	1,083	1,700
	R^b	Radius of curvature (maximum)	0,5	0,5
Key				
NA not applicable				
^a Dimensions L , M and N are derived from the basic dimensions.				
^b Or an equivalent entry chamfer without any sharp corners.				

A.1.2 Gauging test

A.1.2.1 When tested in accordance with [A.1.2.4](#), the conical fitting should satisfy the requirements specified in [A.1.2.2](#) and [A.1.2.3](#).

A.1.2.2 The small end of the male conical fitting should lie between the two limit planes of the gauge and the larger end of the tapered portion should extend beyond the datum plane of the gauge. Rocking should not be evident between the gauge and the fitting made of rigid material undergoing test.

NOTE The test for freedom from rocking can be useful to evaluate semi-rigid fittings.

A.1.2.3 The plane of the maximum diameter at the opening of the female conical fitting should lie between the two limit planes of the gauge. Rocking should not be evident between the gauge and the fitting made of rigid material undergoing test.

A.1.2.4 The procedure should be carried out as specified in [A.1.2.4.1](#) to [A.1.2.4.4](#).

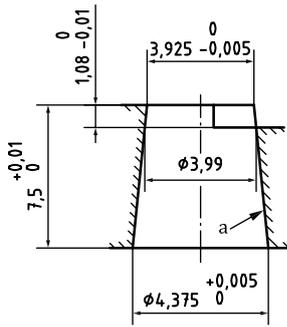
A.1.2.4.1 Carry out the test using steel gauges as illustrated in [Figure A.3](#).

A.1.2.4.2 Carry out the test at a temperature of $(20 \pm 5) ^\circ\text{C}$.

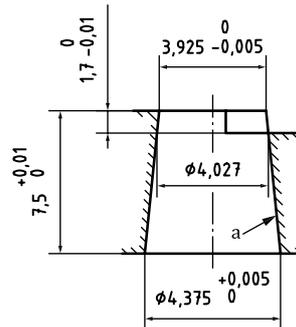
A.1.2.4.3 Prior to testing, condition products made from hygroscopic materials at $(20 \pm 5) ^\circ\text{C}$ and $(50 \pm 10) \%$ relative humidity for not less than 24 h. Conditioning is not required for products made from non-hygroscopic materials.

A.1.2.4.4 Apply the gauge to the conical fitting with a total axial force of 5 N, without the use of torque. Remove the axial load.

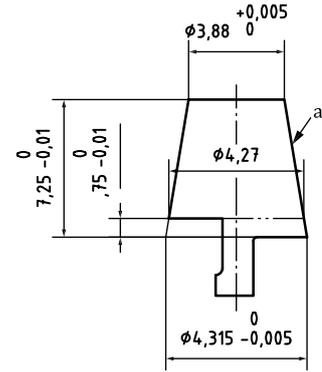
Dimensions in millimetres



a) Gauge for testing rigid male conical fittings



b) Gauge for testing semi-rigid male conical fittings



c) Gauge for testing female conical fittings of all materials

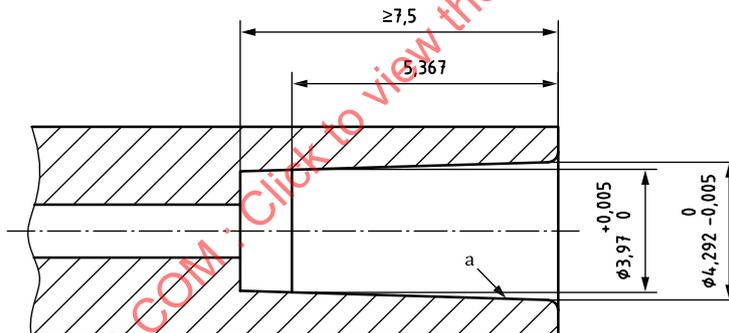
NOTE Cone taper (0,06:1).

Figure A.3 — Gauges for testing 6 % (Luer) conical fittings

A.1.3 Reference steel fittings

Figures A.4 and A.5 depict male and female reference steel fittings.

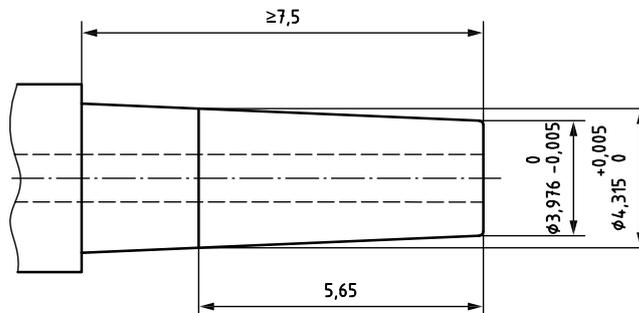
Dimensions in millimetres



NOTE Cone taper (0,06:1).

Figure A.4 — Reference steel female conical fitting

Dimensions in millimetres



NOTE Cone taper (0,06:1).

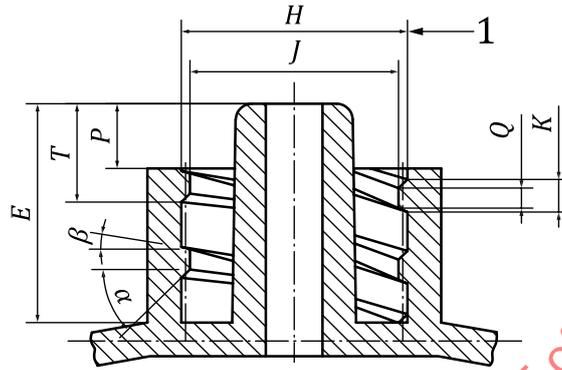
Figure A.5 — Reference steel male conical fitting

A.2 Luer lock fittings

Figures A.6 to A.9 depict Luer lock fittings while Figures A.10 and A.11 depict female reference steel fittings for testing male 6 % (Luer) conical lock fittings. For corresponding dimensions, see Table A.2.

If a female 6 % (Luer) conical lock fitting as shown in Figure A.8 has lugs in a plane inclined to the axis of fitting, the lugs should form a part of the thread form shown in Figure A.9. In this case, 'V' does not apply.

All outside edges of lug or thread form as shown in Figures A.10 and A.11 should have a radius between 0,15 mm and 0,2 mm (unless otherwise specified).

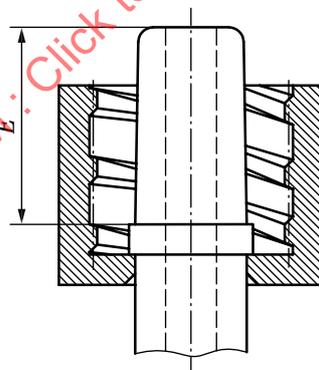


Key

1 double start, right-hand thread of 2,5 mm pitch

NOTE See Key and dimensions given in Table A.2.

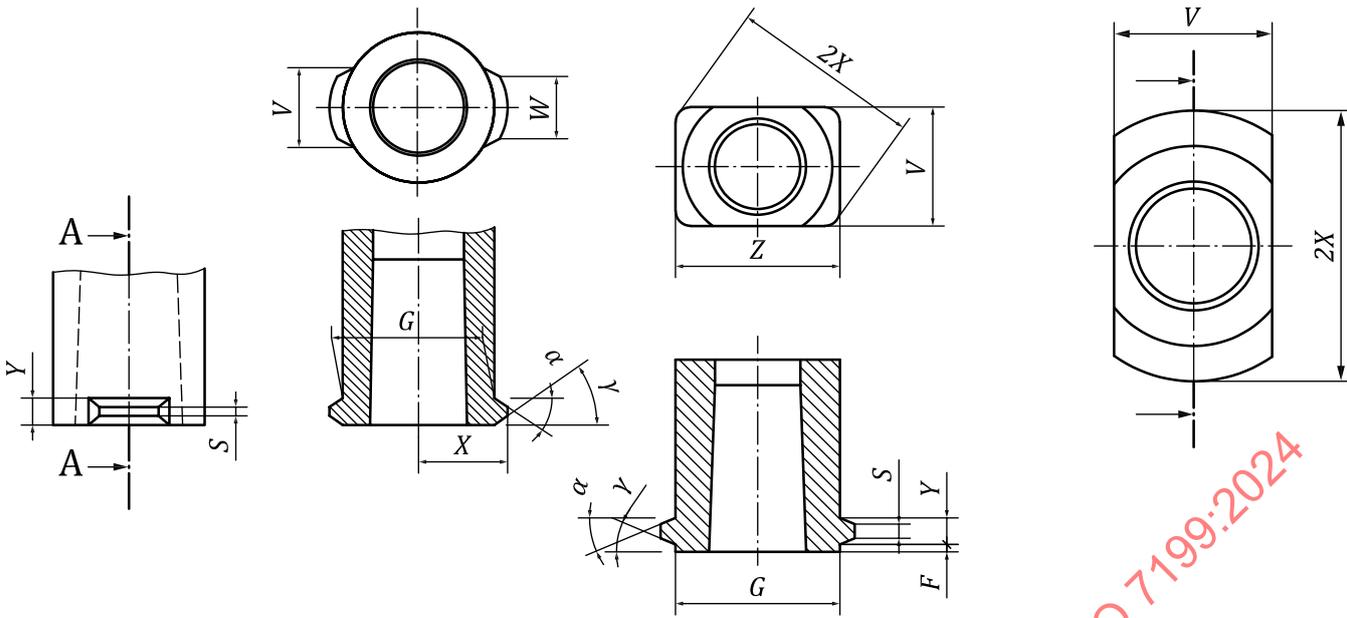
Figure A.6 — Male 6 % (Luer) conical lock fitting with permanently connected internally threaded collar



NOTE 1 For other dimensions, see Figure A.6.

NOTE 2 See Key and dimensions given in Table A.2.

Figure A.7 — Male 6 % (Luer) conical lock fitting with rotatable internally threaded collar



a) Variant A

b) Variant B

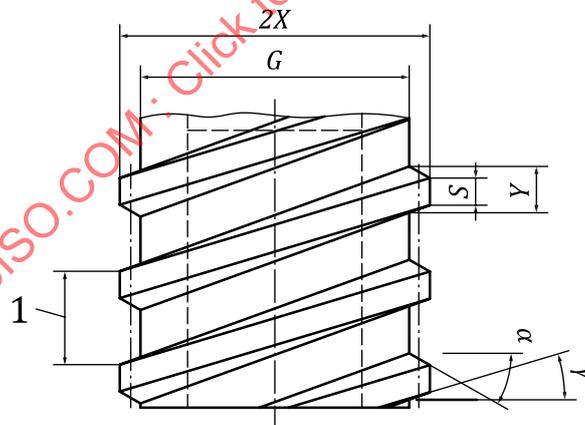
c) Variant C

NOTE 1 Variants B and C are intended to be used for the design of rigid fittings only.

NOTE 2 To ensure compatibility with existing rigid fittings, a maximum $K = 0,8$ mm is preferred.

NOTE 3 See Key and dimensions given in [Table A.2](#).

Figure A.8 — Female 6 % (Luer) conical lock fittings with lugs in a plane perpendicular to the axis of the fitting



Key

1 pitch

NOTE 1 For other dimensions, see [Figure A.8](#).

NOTE 2 See Key and dimensions given in [Table A.2](#).

Figure A.9 — Female 6 % (Luer) conical lock fitting with external thread