



ISO 7199

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

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

**Fourth edition
2024-09**

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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 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.

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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.