
**Cardiovascular implants and
extracorporeal systems —
Cardiopulmonary bypass systems —
Venous bubble traps**

*Implants cardiovasculaires et systèmes extracorporels — Systèmes de
pontage cardiopulmonaire — Pièges à bulles veineuses*

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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 documents 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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For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

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Introduction

This document is intended to ensure that devices designed to remove air entering the venous line during surgical procedures requiring extracorporeal circulatory support have been adequately tested for both their safety and function, and that extracorporeal device characteristics are appropriately disclosed when labeling the device.

This document therefore contains procedures to be used for evaluation of extracorporeal venous bubble traps. Test procedures for determination of the air removal efficiency, blood cell damage and other performance characteristics 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 a venous bubble trap that will suit the needs of the patient.

This document also includes minimum reporting requirements, which will allow the user to compare performance characteristics of venous bubble traps of different designs in a standard way.

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

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

Such studies may be part of a manufacturer's quality system.

This document contains only those requirements that are specific to venous bubble traps. Nonspecific requirements are covered by references to other International Standards listed in the normative references section.

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