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**Evaluation of CPB devices relative  
to their capabilities of reducing the  
transmission of gaseous microemboli  
(GME) to a patient during  
cardiopulmonary bypass**

*Évaluation des dispositifs PCP relative à leurs capacités de réduire la  
transmission des micro-embolies gazeuses (MEG) à un patient durant  
un pontage cardiopulmonaire*

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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](http://www.iso.org/directives)).

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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

Present-generation extracorporeal circuit devices are not designed to generate gas bubbles, as was the case with bubble oxygenators, as a function of their mechanism to achieve gas transfer. Gaseous microemboli (GME), while significantly reduced in current extracorporeal circuits, are still detectable.

The presence of GME in blood is not a normal condition and can trigger potentially adverse conditions as both a foreign surface and as a particle or embolus. Adverse systemic sequelae from GME may include activation of blood cells, immune responses, and blockage of blood vessels.

While attributing a causal relationship between GME and significant adverse clinical sequelae is not clear, laboratory equipment and methodology for testing extracorporeal devices on the bench top and are clinically available for use.

This document will review the current scientific literature on GME detection methodologies and their clinical relevance.

GME testing is currently being performed by companies and research groups. Both users and manufacturers will benefit from the creation of standardized terminology for use in this work.

Development of a consensus position on the clinical implications of GME and the capabilities and limitations of currently utilized monitoring equipment will also serve both users and manufacturers.

The currently available monitoring equipment will have a cost impact on all manufacturers and may burden small enterprises more so than existing larger companies. The equipment cost, however, is less expensive than equipment currently required to evaluate many of the extracorporeal devices such as blood gas analysers, cell counters or spectrometers. Independent investigators with such equipment and expertise are also an option.

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