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

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Abstract: Recommends acceptable methodology for conducting gaseous microemboli (GME) testing and discusses limitations of current test methods. Tests described in this document are limited to those conducted using an in vitro circulatory system.

Keywords: biocompatibility, components, non-pyrogenicity, sterility
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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

ANSI Registration

Publication of this Technical Report that has been registered with ANSI has been approved by the Accredited Standards Developer (AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633). This document is registered as a Technical Report according to the Procedures for the Registration of Technical Reports with ANSI. This document is not an American National Standard and the material contained herein is not normative in nature.

Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.
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Glossary of equivalent standards

International Standards or Technical Reports adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf
Committee representation

Association for the Advancement of Medical Instrumentation
Blood/Gas Exchange Device Committee

The adoption of ISO/TR 19024:2016 as an AAMI Technical Information Report (TIR) was initiated by the AAMI Blood/Gas Exchange Device Committee. The AAMI Blood/Gas Exchange Device Committee also functions as the U.S. Technical Advisory Group to the relevant work in the International Organization for Standardization (ISO). U.S. representatives from the AAMI Blood/Gas Exchange Device Committee (U.S. Sub-TAG for ISO/TC 150/SC 2/WG 4) played an active part in developing the ISO Technical Report. At the time this document was published, the AAMI Blood/Gas Exchange Device Committee (U.S. Sub-TAG for ISO/TC 150/SC 2/WG 4) had the following members:

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Background of AAMI adoption of ISO/TR 19024:2016

As indicated in the foreword to the main body of this document (page viii), the International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this standard, which was developed by ISO Technical Committee (TC) 150 Subcommittee (SC) 2, Cardiovascular implants and extracorporeal systems, to recommend acceptable methodology for conducting gaseous microemboli (GME) testing and discuss limitations of current test methods. Tests described in this document are limited to those conducted using an *in vitro* circulatory system.

U.S. participation in this ISO SC is organized through the U.S. Technical Advisory Group for ISO/TC 150/SC 2, administered by the Association for the Advancement of Medical Instrumentation (AAMI).


AAMI and ANSI procedures require that standards be reviewed and, if necessary, revised every five years to reflect technological advances that may have occurred since publication.

AAMI (and ANSI) have adopted other ISO documents. See the Glossary of Equivalent Standards for a list of ISO standards adopted by AAMI which gives the corresponding U.S. designation and the level of equivalency with the ISO standard.

As used within the context of this document, “shall” indicates requirements strictly to be followed to conform to the standard. “Should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. “May” is used to indicate that a course of action is permissible within the limits of the standard. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe "unavoidable" situations, including those mandated by government regulation.

The concepts incorporated in this Technical Information Report should not be considered inflexible or static. This TIR, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data come to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

NOTE Beginning with the ISO foreword on page viii, this American National Standard is identical to ISO/TR 19024:2016.
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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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

1 Scope and purpose

This document recommends acceptable methodology for conducting gaseous microemboli (GME) testing and discusses limitations of current test methods. Tests described in this document are limited to those conducted using an in vitro circulatory system.

This document is applicable to all devices intended for extracorporeal circulatory support during cardiopulmonary bypass (CPB). It outlines approaches currently used to assess the ability of CPB devices to handle GME.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1 cardiopulmonary bypass
extracorporeal circuit used to support a subject's circulatory and gas exchange requirements when the heart and lungs are temporarily functionally excluded from normal circulation during cardiac surgery

3.2 gaseous microemboli
air bubbles present in circulating blood that are in the range 10 µm to 500 µm diameter

3.3 ultrasonic detector
device based on Doppler phenomenon (pulsed or continuous wave) that emits sound signals from a piezoelectric crystal that are reflected from moving blood

Example 1 Transcranial Doppler, transesophageal echocardiography, or clamp-on sensors for extracorporeal tubing with the latter used for bench top in vitro testing.