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BSI Standards Publication

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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National foreword

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A list of organizations represented on this committee can be obtained on request to its secretary.

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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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Contents

Page

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.

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

1 Scope

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
- IEC Electropedia: available at http://www.electropedia.org/

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.

EXAMPLE 2 Ultrasonic detectors are able to discriminate circulating particles from background blood flow, and detected reflections (or signals) can be analysed in real time to produce a display of approximate quantities and sizes during the sampling time frame.

3.4
whole blood
fluid used for bench-top studies involving gaseous microbubbles is anticoagulated whole blood