

This is a preview of "ISO 18562-1:2017". [Click here to purchase the full version from the ANSI store.](#)

First edition
2017-03

Biocompatibility evaluation of breathing gas pathways in healthcare applications —

Part 1: Evaluation and testing within a risk management process

*Évaluation de la biocompatibilité des voies de gaz respiratoires dans
les applications de soins de santé —*

*Partie 1: Évaluation et essais au sein d'un processus de gestion du
risque*



Reference number
ISO 18562-1:2017(E)

© ISO 2017

This is a preview of "ISO 18562-1:2017". Click [here](#) to purchase the full version from the ANSI store.



COPYRIGHT PROTECTED DOCUMENT

© ISO 2017, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

This is a preview of "ISO 18562-1:2017". Click here to purchase the full version from the ANSI store.

Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	2
3 Terms and definitions	2
4 General principles applying to BIOCOMPATIBILITY evaluation of MEDICAL DEVICES	6
4.1 General.....	6
4.2 TYPE TESTS.....	7
4.3 BIOCOMPATIBILITY HAZARD identification.....	8
4.4 Extent of RISK ASSESSMENT.....	8
4.5 BIOCOMPATIBILITY evaluation plan.....	9
4.6 Selection of tests.....	10
4.7 Subsequent evaluation.....	10
5 Contamination of breathing gas from GAS PATHWAYS	11
5.1 * Duration of use.....	11
5.2 PARTICULATE MATTER (PM) emissions.....	13
5.3 VOLATILE ORGANIC COMPOUND (VOC) emissions.....	13
5.4 LEACHABLE SUBSTANCES in condensate.....	13
6 Adjustment for different PATIENT groups	13
6.1 General considerations.....	13
6.2 Adjustment for body weight.....	13
6.3 * Deriving a permitted concentration from a TOLERABLE EXPOSURE.....	14
7 * Deriving allowable limits	14
7.1 General PROCESS.....	14
7.2 For MEDICAL DEVICES intended for limited exposure use (≤ 24 h).....	15
7.3 For MEDICAL DEVICES intended for prolonged exposure use (> 24 h but < 30 d).....	16
7.4 For MEDICAL DEVICES intended for permanent contact (≥ 30 d).....	16
8 RISK benefit analysis	16
9 Assess the BIOCOMPATIBILITY of the MEDICAL DEVICE	17
Annex A (informative) Rationale and guidance	18
Annex B (informative) Reference to the essential principles	20
Annex C (informative) Terminology — Alphabetized index of defined terms	21
Bibliography	23

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 voluntary nature of ISO standards, 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 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

A list of all parts in the ISO 18562 series can be found on the ISO website.

This is a preview of "ISO 18562-1:2017". [Click here to purchase the full version from the ANSI store.](#)

Introduction

This document represents the application of the best-known science, in order to improve PATIENT safety, by addressing the RISK of potentially hazardous substances being conveyed to the PATIENT by the gas stream.

This document is intended to cover the biological evaluation of GAS PATHWAYS of MEDICAL DEVICES within a RISK MANAGEMENT PROCESS, as part of the overall MEDICAL DEVICE evaluation and development. This approach combines the review and evaluation of existing data from all sources with, where necessary, the selection and application of additional tests.

In general, the ISO 10993 series is intended to cover the biological evaluation of MEDICAL DEVICES. However, the ISO 10993 series does not sufficiently address the biological evaluation of the GAS PATHWAYS OF MEDICAL DEVICES.

Before this document was developed, some AUTHORITIES HAVING JURISDICTION interpreted the ISO 10993-1:2009, Table A.1 to mean that materials in the GAS PATHWAY form “indirect contact” with the PATIENT, and should be subjected to tests equivalent to those required for tissue contact parts of MEDICAL DEVICES. This interpretation can lead to tests with questionable benefit and also to possible HAZARDS not being detected.

ISO 10993-1:2009 states that it is not intended to provide a rigid set of test methods as this might result in an unnecessary constraint on the development and use of novel MEDICAL DEVICES. ISO 10993-1:2009 also states where a particular application warrants it, experts in the product or in the area of application concerned can choose to establish specific tests and criteria, described in a product-specific vertical standard. This new series of standards is intended to address the specific needs for the evaluation of GAS PATHWAYS that are not adequately covered by ISO 10993-1:2009.

This document provides a guide to the development of a biological evaluation plan that minimizes the number and exposure of test animals by giving preference to chemical constituent testing and *in vitro* models.

The initial version of this series of standards was intended to cover only the most commonly found potentially harmful substances. It was felt that it was best to get a functioning document published that would test for the bulk of the currently known substances of interest. With the use of the TTC (THRESHOLD OF TOXICOLOGICAL CONCERN) approach, this document has the potential to be used to assess the safety of essentially any compound released from the GAS PATHWAYS of respiratory MEDICAL DEVICES, with very few exceptions (e.g. PCBs, dioxins), and not just the most commonly found potentially harmful substances. Later amendments and additional parts are planned to explicitly cover less common substances.

In this document, the following print types are used:

- requirements and definitions: roman type;
- *test specifications: italic type;*
- informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
- terms defined in [Clause 3](#) of this DOCUMENT or as noted: small capitals.

In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this document conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this document;

This is a preview of "ISO 18562-1:2017". [Click here to purchase the full version from the ANSI store.](#)

- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in [Annex A](#).

The attention of Member Bodies is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.