Second edition
2018-08

Sterilization of health care products — Biological and chemical indicators — Test equipment

Stérilisation des produits de santé — Indicateurs biologiques et chimiques — Appareillage d'essai

Reference number
ISO 18472:2018(E)

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

Published in Switzerland

Contents

Page

Foreword ... **iv**

Introduction ... **v**

1 Scope ... **1**

2 Normative references ... **1**

3 Terms and definitions ... **2**

4 Performance requirements for resistometers ... **4**
4.1 Intended use ... 4
4.2 Test methods ... 4
4.3 Air leakage test ... 4
4.4 Steam resistometer performance requirements ... 5
4.4.1 Measurement accuracy ... 5
4.4.2 Data ... 5
4.4.3 Process control ... 5
4.4.4 General steam resistometer requirements ... 6
4.4.5 Air leakage test ... 7
4.4.6 Operation of steam resistometer ... 7
4.5 Ethylene oxide gas resistometer performance requirements ... 7
4.5.1 Measurement accuracy ... 7
4.5.2 Data ... 8
4.5.3 Process control ... 8
4.5.4 General ethylene oxide gas resistometer requirements ... 9
4.5.5 Air leakage test ... 10
4.5.6 Operation of ethylene oxide gas resistometer ... 10
4.6 Dry heat (heated air) resistometer performance requirements ... 10
4.6.1 Measurement accuracy ... 10
4.6.2 Data ... 11
4.6.3 Process control ... 11
4.6.4 General dry heat (heated air) resistometer requirements ... 12
4.6.5 Operation of dry heat (heated air) resistometer ... 12
4.7 Vaporized hydrogen peroxide resistometer performance requirements ... 13
4.7.1 Measurement accuracy ... 13
4.7.2 Recording interval ... 13
4.7.3 Process control ... 13
4.7.4 General vaporized hydrogen peroxide resistometer requirements ... 14
4.7.5 Air leakage test ... 15
4.7.6 Operation of vaporized hydrogen peroxide resistometer ... 15

5 Calibration ... **15**

Annex A (informative) **Additional performance characterization — Steam** ... **16**

Annex B (informative) **Additional performance characterization — Ethylene oxide gas** ... **19**

Annex C (informative) **Additional performance characterization — Dry heat** ... **22**

Annex D (informative) **Resistometer documentation and derivations** ... **24**

Bibliography ... **30**

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 of the voluntary nature of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 18472:2006), which has been technically revised.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

To test the performance of biological and chemical indicators, specific test equipment is required. This document specifies the performance requirements for the test equipment to be used to establish the response of biological and chemical indicators to critical process variables. This document does not apply to test equipment for indicators used in irradiation, isolator/room biodecontamination (at atmospheric pressure), or low temperature steam and formaldehyde processes.

Resistometers constitute test equipment designed to create precise and repeatable sterilizing environments, allowing the evaluation of their effect on biological inactivation kinetics, chemical reactions, material degradation and product bioburden. Resistometers allow precise variation of the environmental conditions and cycle sequences in order to produce controlled physical studies. When used with the defined test methods given in the appropriate parts of ISO 11138 for biological indicators and ISO 11140 for chemical indicators, the results of these studies can be used to demonstrate conformance of biological indicators and chemical indicators to these standards.

Resistometers differ from conventional sterilizers. Instrumentation selection and control requirements for resistometers are based upon mathematical models in which rates of reaction, measurement accuracy and process control requirements are evaluated to quantify the effects induced by test equipment-controlled variables. The requirements for accurate measurement, precise control, and rapid rates of change approach limits of commercially available process control and calibration instrumentation measurement accuracy. The measurement and control requirements often prohibit practical validation of a resistometer using procedures that might be employed in a conventional heat or chemical sterilization system. Resistometers are considered test equipment rather than sterilizers; therefore, an understanding of instrumentation and process design is critical in clarifying requirements on precision and measurement accuracy. Practical design takes the following into consideration:

— achievable measurement and control;

— acceptable equipment induced variation in test results;

— economic design (utilizing tight process controls only where required);

— test method correlation with intended use;

— historical knowledge applied to test procedures and an understanding of micro-environmental physical phenomena;

— testing and analysis alternatives, when accurate quantitative determinations exceed physical measurement/control limits.