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

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



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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

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This first edition of ISO 18472 partially replaces ISO 11140-2.

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Introduction

To test the performance of chemical and biological indicators, specific test equipment is required. This International Standard specifies the performance requirements for the test equipment to be used in order to establish the response of chemical and biological indicators to critical process variables. This International Standard does not apply to test equipment for irradiation indicators or low temperature steam and formaldehyde indicators.

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 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 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 accuracy. Practical design has to consider the following:

- 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.