INTERNATIONAL STANDARD

ISO 11140-2

First edition
1998-12-01

Sterilization of health care products — Chemical indicators —

Part 2:
Test equipment and methods

Stérilisation des produits de santé — Indicateurs chimiques —

Partie 2: Appareillage et méthodes d'essai

Reference number
ISO 11140-2:1998(E)

Contents

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Printed in Switzerland

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.

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.

International Standard ISO 11140-2 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products.*

ISO 11140 consists of the following parts, under the general title *Sterilization of health care products — Chemical indicators*:

— *Part 1: General requirements*

— *Part 2: Test equipment and methods*

— *Part 3: Steam penetration test with user-assembled and preassembled test packs*

— *Part 4: Class 2 indicators for air-removal test*

Introduction

To test the performance of chemical indicators, with the exception of irradiation indicators, specific test equipment is required. This part of ISO 11140 specifies the performance requirements for the test equipment to be used to establish the response to the essential physical parameters. Irradiation indicators are generally tested in irradiation facilities.

The performance tolerances for equipment given in this part of ISO 11140 are intended to be suitable for testing any of the classes of indicator specified in ISO 11140-1. Equipment operating with wider tolerances may be suitable for specific applications.

Sterilization of health care products — Chemical indicators —

Part 2:
Test equipment and methods

1 Scope

This part of ISO 11140 specifies requirements for the test equipment and methods to be used to test chemical indicators for conformity to the requirements given in ISO 11140-1.

The test equipment and methods for ISO 11140-3 and ISO 11140-4 are specified in those parts.

This part of ISO 11140 does not specify requirements for test equipment or methods to be used to test Class 1 chemical indicators for ionizing irradiation sterilization for conformity to ISO 11140-1.

This part of ISO 11140 does not address safety aspects of the test equipment, because these are covered by specific regional, national or local regulations.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 11140. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 11140 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 11140-1:1995, *Sterilization of health care products — Chemical indicators — Part 1: General requirements.*

ISO 11134:1994, *Sterilization of health care products — Requirements for validation and routine control — Industrial moist heat sterilization.*

3 Definitions

For the purposes of this part of ISO 11140, the definitions given in ISO 11140-1 and the following definition apply.

3.1
come-up time
time elapsed from the commencement of steam admission to the attainment of the selected exposure conditions

4 Chemical Indicator Evaluating Resistometer (CIER)

4.1 General

The resistometer is intended to be used to expose test samples to stated test conditions.

The following specifications define the conditions to be achieved in proximity to the sample, but the means by which these conditions are to be measured and controlled are not addressed.

NOTE Due to the required accuracy, automated control of the process parameters is recommended.

4.2 Steam chemical indicator resistometer

4.2.1 Performance requirements

4.2.1.1 The equipment shall be capable of maintaining the conditions given in table 1 within the limits given.

Table 1 — Tolerances and minimum ranges required

Temperature	(110 to 145) °C ± 0,5 °C
Pressure	(140 to 420) kPa ± 3,5 kPa
Vacuum	(4 to 100) kPa ± 0,5 kPa
NOTE The pressure values given are the absolute pressures.	

NOTE A lower absolute pressure in the vacuum phase may be required to test Class 5 and 6 indicators due to the partial pressure of the retained air.

4.2.1.2 A timer covering 90 min with an accuracy of at least ± 1 % of the exposure time shall be used for measuring the exposure time for all steam indicators specified in ISO 11140-1.

4.2.1.3 The equipment shall be provided with means to evacuate the chamber to less than the vacuum setpoint to permit adequate air removal prior to admission of steam. Steam admission to the chamber shall not be used to effect air removal.

NOTE Some indicators can be adversely affected by prolonged exposure to dry heat and vacuum. The minimum practicable settings for evacuation should be used, which normally should not exceed 5 min.

4.2.1.4 The chamber shall be so designed that condensate formed on colder parts of the chamber shall not affect the test conditions.

NOTE This may require that the inner surfaces of the chamber and/or door are thermostatically controlled to the selected operating temperature.

4.2.1.5 The chamber shall be supplied with saturated steam from a source external to the chamber. The steam supply shall meet the requirements of ISO 11134.

4.2.1.6 Temperature and absolute pressure shall be monitored, recorded and verified to be within the required accuracy limits for the selected exposure conditions as given in table 1.

4.2.1.7 The come-up time shall not exceed 10 s. During this come-up period, the time from 100 °C to the attainment of the selected exposure temperature shall not exceed 5 s.

4.2.1.8 At the end of the exposure period, the time taken to attain atmospheric pressure in the CIER chamber shall not exceed 5 s.

4.2.2 Procedure

4.2.2.1 Load the indicator on a suitable sample holder. The sample holder shall not affect the performance of the indicator.

NOTE The sample holder should allow the indicator to be exposed to the test conditions in the manner intended by the indicator manufacturer. Different indicators may require different designs of sample holders. Consult the indicator manufacturer for guidance.

4.2.2.2 Before initiating a test cycle, heat the inner surface of the chamber to the required temperature.

4.2.2.3 With the loaded sample holder in the chamber, carry out the following sequence of operations.

a) Evacuate the chamber to the pre-exposure setpoint.

b) Admit steam to the chamber to obtain the required temperature and pressure.

c) Maintain the conditions for the required exposure time.

d) At the end of the exposure period, evacuate the chamber to a pressure not exceeding the post-exposure setpoint and then admit air to ambient pressure.

4.2.2.4 On removal from the chamber, examine the indicator. The result shall be recorded with reference to the selected exposure conditions (see 4.2.1.6).

4.3 Ethylene oxide (EO) chemical indicator resistometer

4.3.1 Performance requirements

4.3.1.1 The equipment shall be capable of maintaining the conditions given in table 2 within the limits given for exposure periods between 1 min and 120 min.

Table 2 — Tolerances and minimum ranges required

Ethylene oxide concentration	(200 to 1 200) mg/l ± 5 %
Temperature	(30 to 65) °C ± 1 °C
Relative humidity (RH)	(20 to 85) % ± (10 % × RH)

NOTE 1 The maximum EO concentration specified in table 2 will determine the operating pressure depending on the diluent gases used, if any, and therefore operating pressure is not listed above.

NOTE 2 If this accuracy is not obtained (e.g. at low EO concentrations with the gas mixture containing less than 10 % EO), the application should be restricted to specific indicator classes (e.g. process indicators) which require less accuracy.

4.3.1.2 A timer covering 120 min with an accuracy of at least ± 1 % of the exposure time shall be used for measuring the exposure time for all EO indicators specified in ISO 11140-1.

4.3.1.3 The equipment shall be provided with means to evacuate the chamber to a level less than 4 kPa to ensure adequate dispersion of the sterilant and to exhaust the sterilant at the end of the exposure period.

4.3.1.4 The total time to achieve the required EO gas concentration surrounding the indicator and to reduce this concentration to a level that will no longer affect the indicator shall not be more than 10 % of the total integrated exposure (partial EO pressure multiplied by exposure time).

4.3.1.5 The chamber and door shall be provided with means to maintain the temperature of the inner surface of the chamber at the required operating temperature.

4.3.1.6 Means shall be provided to ensure that neither liquid EO nor particles of polymers are admitted to the chamber.

4.3.1.7 Temperature, pressure and relative humidity shall be monitored, recorded and verified to be within the required accuracy limits for the selected exposure conditions. Both temperature and pressure shall be recorded throughout the test cycle.

4.3.2 Procedure

4.3.2.1 Load the indicator on a suitable sample holder. The sample holder shall not affect the performance of the indicator.

NOTE The sample holder should allow the indicator to be exposed to the test conditions in the manner intended by the manufacturer. Different indicators may require different designs of sample holders. Consult the indicator manufacturer for guidance.

4.3.2.2 Before initiating a test cycle, the sample, sample holder and the inner surface of the chamber shall be equilibrated to the required temperature.

4.3.2.3 With the loaded sample holder in the chamber, carry out the following sequence of operations.

a) Evacuate the chamber to the required pressure.

b) Admit sufficient water vapour to raise the relative humidity in the chamber to the required level.

c) Admit EO or the EO diluent gas mixture to the required EO concentration. For the 0 min exposure time, no EO should be admitted. If applicable, the diluent gas shall be admitted to the working pressure. This test should not be carried out in a vessel where traces of EO may be present.

d) Maintain these conditions for the required exposure time.

e) At the end of the exposure period, reduce the EO concentration surrounding the indicator to a level that will no longer affect the indicator.

4.3.2.4 On removal from the chamber, examine the indicator. The result shall be recorded with reference to the selected exposure conditions (see 4.3.1.7).

4.4 Dry heat chemical indicator resistometer

4.4.1 Performance requirements

4.4.1.1 The equipment shall be capable of maintaining the conditions given in table 3 within the limits given for exposure periods up to 180 min. The equipment shall have at least an accuracy of ± 2,5 °C for the testing of Class 1, Class 3, Class 4 and Class 5 indicators, and ± 0,5 °C for the testing of Class 6 indicators.

Table 3 — Tolerances and minimum ranges required

Class 1, 3, 4 and 5 indicators	(120 to 200) °C ± 2,5 °C
Class 6 indicators	(120 to 200) °C ± 0,5 °C

4.4.1.2 A timer covering 180 min with an accuracy of at least ± 1 % of the exposure time shall be used for measuring the exposure time for all dry heat indicators specified in ISO 11140-1.

4.4.1.3 The chamber and door shall be provided with means to maintain the temperature of the inner surface of the chamber at the required operating temperature.

4.4.1.4 The chamber shall be supplied with heated gas (generally air) for which the indicator is intended to be used.

4.4.1.5 The forced gas circulation shall be so designed that the temperature of the colder parts shall not adversely affect the testing conditions.

4.4.1.6 Temperatures shall be monitored, recorded and verified to be within the required accuracy limits for the selected exposure conditions, and shall be recorded throughout the test cycle.

4.4.1.7 The time for the CIER to return to the set temperature after introduction of the indicator shall not exceed 2 min.

4.4.2 Procedure

4.4.2.1 Load the indicator on a suitable sample holder. The sample holder shall not affect the performance of the indicator.

NOTE The sample holder should allow the indicator to be exposed to the test conditions in the manner intended by the indicator manufacturer. Different indicators may require different designs of sample holders. Consult the indicator manufacturer for guidance.

4.4.2.2 Preheat the chamber to the required temperature.

4.4.2.3 With the loaded sample holder in the chamber, expose the indicator to the heated gas.

4.4.2.4 Maintain the conditions for the required exposure time.

4.4.2.5 At the end of the exposure period, remove the samples from the chamber and cool to 100 °C or less over a period not exceeding 1 min.

4.4.2.6 On removal from the chamber, examine the indicator. The result shall be recorded with reference to the selected exposure conditions (see 4.4.1.6).

4.5 Steam formaldehyde chemical indicator resistometer

4.5.1 Performance requirements

4.5.1.1 The equipment shall be capable of maintaining the conditions given in table 4 within the limits given for exposure periods between 1 min and 360 min.

Table 4 — Tolerances and minimum ranges required

Formaldehyde concentration	(5 to 70) mg/l ± 2 mg/l
Temperature	(50 to 85) °C ± 1 °C
Relative humidity (RH)	(90 to 95) % ± (5 % × RH)

NOTE The maximum concentration specified in table 4 is dependent on the temperature. At low temperatures high concentrations may lead to formaldehyde polymerization.

4.5.1.2 A timer covering 360 min with an accuracy of at least ± 1 % of the exposure time shall be used for measuring the exposure time for all steam formaldehyde indicators specified in ISO 11140-1.

4.5.1.3 The equipment shall be provided with means to evacuate the chamber to less than 4 kPa to permit adequate air removal prior to admission of the sterilant and to exhaust the sterilant at the end of the exposure period.

4.5.1.4 The time to achieve the required formaldehyde concentration from commencement of formaldehyde admission shall not exceed 60 s and the time to exhaust the gas to 5 kPa at the end of the exposure period shall not exceed 60 s.

4.5.1.5 The chamber, door and piping shall be provided with means to maintain the temperature of the inner surface of the chamber at the required operating temperature.

As formaldehyde readily dissolves in water, the actual formaldehyde concentration in the chamber throughout the process will be influenced largely by the formation of condensate; therefore preheating of the chamber is essential.

4.5.1.6 Means shall be provided to ensure that neither liquid formalin nor particles of polymers are admitted to the chamber.

4.5.1.7 Temperature and pressure shall be monitored, recorded and verified to be within the required accuracy limits for the selected exposure conditions. Temperature and pressure shall be recorded throughout the test cycle.

4.5.2 Procedure

4.5.2.1 Load the indicator on a suitable sample holder. The sample holder shall not affect the performance of the indicator.

NOTE The sample holder should allow the indicator to be exposed to the test conditions in the manner intended by the indicator manufacturer. Different indicators may require different designs of sample holders. Consult the indicator manufacturer for guidance.

4.5.2.2 Preheat the chamber to the desired temperature.

4.5.2.3 Place the loaded sample holder in the chamber and seal the chamber.

4.5.2.4 With the loaded sample holder in the chamber, carry out the following sequence of operations.

a) Evacuate the chamber to the required pressure.

b) Admit sufficient water vapour to raise the relative humidity in the chamber to the required level.

c) Evacuate the chamber to a pressure sufficient to allow admission of the formaldehyde/water vapour mixture.

NOTE To avoid condensation, the total chamber pressure should not exceed the saturated pressure for water vapour at the actual temperature.

d) Admit formaldehyde to the required concentration and bring the chamber to the required temperature/pressure by adding water vapour to the chamber. For the 0 min exposure time, no formaldehyde should be admitted.

e) Maintain these conditions for the required exposure time.

f) At the end of the exposure period, reduce the formaldehyde concentration surrounding the indicator to a level that will no longer affect the indicator.

4.5.2.5 On removal from the chamber, examine the indicator. The result shall be recorded with reference to the selected exposure conditions (see 4.5.1.7).

NOTE Specific procedures may be needed to remove formaldehyde or polymer residues from the CIER as they may affect the reproducibility of subsequent cycles.

4.6 Recording systems

4.6.1 General requirements

4.6.1.1 The instrument shall have a valid test certificate.

4.6.1.2 Calibration shall be carried out using a working or reference standard which is traceable to the national standard or primary standard.

NOTE For example, calibration procedures are provided in ISO 10013:1995, *Guidelines for developing quality manuals.*

4.6.2 Temperature recording systems

4.6.2.1 Temperature recorder(s) shall be used to record the temperatures measured in the locations specified in the procedures described in this part of ISO 11140.

4.6.2.2 The temperature recorder shall have two or more channels (each having a sampling and recording rate relevant to the process dynamics).

4.6.2.3 The scale range of the instruments shall include the required temperatures and be such that the maximum temperature is not more than 90 % of the full-scale range.

4.6.2.4 The minor mark interval shall not exceed 1 °C and the chart speed shall be such that the process will render a chart of at least 200 mm. The resolution shall not be less than 0,5 °C.

4.6.2.5 The limit of error of the temperature recorder over the temperature ranges specified in tables 1 to 4 shall not exceed 0,25 % when tested in the ambient temperature at which it will be used.

4.6.3 Pressure recording systems

4.6.3.1 A pressure recording instrument shall be used in conjunction with a pressure-sensitive measuring element to record the pressure within the chamber during a test cycle. The instrument may be integrated into the temperature recording instrument as an additional channel calibrated for pressure. The sampling rate for each channel shall be 1 s or better. All data sampled shall be used for the interpretation of the results.

4.6.3.2 The scale range of the instruments shall include the required pressures and be such that the maximum pressure is not more than 90 % of the full-scale range. The minor mark interval shall not exceed 4 kPa and the chart speed shall be such that the process will render a chart of at least 200 mm. The resolution shall not be less than 2 kPa.

4.6.3.3 The limit error over the pressure ranges specified for the CIER shall not exceed 0,5 % when tested in the ambient temperature at which it will be used.

4.6.3.4 The temperature coefficient of the measuring system shall not exceed 0,01 % per degree Celsius at the temperatures at which the pressure sensor is to be used.

4.6.3.5 The error due to the change in the ambient temperature shall not exceed 0,02 % per degree Celsius.

4.6.3.6 The time constant (0 % to 63 %) for rising pressure shall not be greater than 0,04 s.

ICS 11.080

Descriptors: health care products, medical equipment, sterilization, chemical indicators, classification, specifications, performance, generalities.

Price based on 7 pages