



MALAYSIAN STANDARD

MS ISO 11140-5:2010
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Sterilization of health care products - Chemical indicators - Part 5: Class 2 indicators for Bowie and Dick-type air removal tests (ISO 11140-5:2007, IDT)

ICS: 11.080.01

Descriptors: medical device, sterilization, chemical indicators, Class 2 indicators, Bowie, Dick-type, air removal tests

NOTE. This Malaysian Standard has been reviewed and confirmed as being current.

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MS ISO 11140-5:2010

Committee representation

The Industry Standards Committee on Medical Devices and Facilities for Healthcare (ISC R) under whose authority this Malaysian Standard was adopted, comprises representatives from the following organisations:

Association of Malaysia Medical Industries
Atomic Energy Licensing Board
Biomedical Engineering Association Malaysia
Department of Standards Malaysia
Federation of Malaysian Manufacturers
Institute for Medical Research
Malaysia Medical Device Association
Malaysian Association of Standards Users
Malaysian Medical Association
Malaysian Nuclear Agency
Malaysian Organisation of Pharmaceutical Industries
Malaysian Rubber Board
Malaysian Rubber Export Promotion Council
Ministry of Health Malaysia
Ministry of Health Malaysia (Medical Device Bureau)
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SIRIM QAS International Sdn Bhd
Universiti Kebangsaan Malaysia
Universiti Teknologi Malaysia

The Technical Committee on Quality Management and Corresponding General Aspects for Medical Devices which recommended the adoption of the ISO Standard as Malaysian Standard consists of representatives from the following organisations:

Association of Private Hospitals of Malaysia
Biomedical Engineering Association Malaysia
Federation of Malaysian Manufacturers
Institute of Quality Malaysia
Malaysia Medical Device Association
Malaysian Medical Association
Malaysian Nuclear Agency
Malaysian Rubber Export Promotion Council
Malaysian Rubber Glove Manufacturers' Association
Ministry of Health Malaysia
SIRIM Berhad (Secretariat)
SIRIM QAS International Sdn Bhd
SterilGamma (M) Sdn Bhd

NATIONAL FOREWORD

The adoption of the ISO Standard as a Malaysian Standard was recommended by the Technical Committee on Quality Management and Corresponding General Aspects for Medical Devices under the authority of the Industry Standards Committee on Medical Devices and Facilities for Healthcare.

This Malaysian Standard is identical with ISO 11140-5:2007, *Sterilization of health care products - Chemical indicators - Part 5: Class 2 indicators for Bowie and Dick-type air removal tests*, published by the International Organization for Standardization (ISO). However, for the purposes of this Malaysian Standard, the following apply:

- a) in the source text, "this International Standard" should read "this Malaysian Standard";
and
- b) the comma which is used as a decimal sign (if any), to read as a point.

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

Part 1: General requirements

Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test

Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration

Part 5: Class 2 indicators for Bowie and Dick-type air removal tests

Compliance with a Malaysian Standard does not of itself confer immunity from legal obligations.

NOTE. IDT on the front cover indicates an identical standard i.e. a standard where the technical content, structure, and wording (or is an identical translation) of a Malaysian Standard is exactly the same as in an International Standard or is identical in technical content and structure although it may contain the minimal editorial changes specified in clause 4.2 of ISO/IEC Guide 21-1.

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.

ISO 11140-5 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 11140-5:2000), which has been technically revised.

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

- *Part 1: General requirements*
- *Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test*
- *Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration*
- *Part 5: Class 2 indicators for Bowie and Dick-type air removal tests*

Introduction

The air removal test is used to evaluate the efficacy of air removal during the pre-vacuum phase of a pre-vacuum sterilization cycle or during the pulsing stage of positive pulsing cycles if non-condensable gases were present in the steam. Retention of air due to an inefficient air removal stage or the presence of an air leak or non-condensable gases during the air removal stage are circumstances which can lead to failure of the test. This part of ISO 11140 describes the requirements for Class 2 indicators for Bowie and Dick-type air removal test sheets and packs.

For a description of the classes of chemical indicators, see ISO 11140-1.

The difference between the steam penetration test (ISO 11140-3 and ISO 11140-4) and the air removal test (ISO 11140-5) is described in the chemical indicator guidance document (ISO 15882).

Sterilization of health care products — Chemical indicators —

Part 5: Class 2 indicators for Bowie and Dick-type air removal tests

1 Scope

This part of ISO 11140 specifies the requirements for Class 2 indicators for Bowie and Dick-type air removal tests used to evaluate the effectiveness of air removal during the pre-vacuum phase of pre-vacuum steam sterilization cycles.

Additionally, this part of ISO 11140 includes test methods and equipment used to meet these performance requirements.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 5-4:1995, *Photography — Density measurements — Part 4: Geometric conditions for reflection density*

ISO 5636-3, *Paper and board — Determination of air permeance (medium range) — Part 3: Bendtsen method*

ISO 11140-1:2005, *Sterilization of health care products — Chemical indicators — Part 1: General requirements*

IEC 60584-2:1982, *Thermocouples. Part 2: Tolerances*

IEC 60751:1983, *Industrial platinum resistance thermometer sensors*

3 Terms and definitions

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

3.1

indicator system

combination of the indicator agent and its substrate subsequently intended to be used in combination with a specific test load

NOTE For the purposes of this document, the specific test load is the standard test pack as defined in Annex E.

3.2

indicator

combination of the indicator agent and its substrate in the final form in which it is intended to be used

See Annex E of ISO 11140-1:2005.

NOTE The indicator may be user-assembled or pre-assembled. The test load may be disposable, for limited re-use or re-usable.

3.3
equilibration time
period which elapses between the attainment of the sterilization temperature in the sterilizer chamber and the attainment of the sterilization temperature in all parts of the load

4 General requirements

Unless otherwise specified in this part of ISO 11140, the general requirements given in ISO 11140-1 apply.

5 Indicator system

5.1 Format

5.1.1 The indicator agent shall be uniformly distributed on its substrate to cover not less than 30 % of one side of the substrate.

The pattern of indicator agent distribution should allow easy judgement of the uniformity of the colour change.

5.1.2 The substrate of the indicator system shall have a uniform ground colour which provides a difference in colour density of not less than 0,3 between ground colour and either the changed or the unchanged indicator agent, as specified by the manufacturer, when the difference in colour density is determined using a reflective densitometer.

Compliance shall be tested in accordance with Annex A.

5.1.3 The indicator system dimensions shall be (200 ± 20) mm \times (275 ± 25) mm.

5.1.4 The indicator system shall have an air porosity not less than $1,7 \mu\text{m}/(\text{Pa}\cdot\text{s})$ when tested in accordance with ISO 5636-3 at an air pressure of 1,47 kPa.

5.2 Performance

5.2.1 The indicator system shall show a uniform colour change (as specified by the manufacturer) after exposure to saturated steam at 134 °C for $3,5 \text{ min} \pm 5 \text{ s}$ and/or exposure to saturated steam at 121 °C for $15 \text{ min} \pm 5 \text{ s}$, or such other combinations of time and temperature as the manufacturer shall specify for the intended use of product. In all cases, the permitted tolerance on the test temperature shall be $^{+1,5}_0$ °C and the time given shall be the time within which the colour change shall occur.

Compliance shall be tested in accordance with Annex B.

5.2.2 When placed in the centre of the standard test pack as specified in Annex E, the indicator system shall show a non-uniform colour change when the temperature at the centre of the standard test pack is (2^{+1}_0) °C lower than the temperature of the chamber drain at the beginning of the final 1 min of a 3,5 min cycle at 134 °C, or at the beginning of the final 5 min of a 15 min cycle at 121 °C of the exposure phase of the steam exposure apparatus. This is the standard fault condition generated by inadequate air removal from the chamber. Any other combination of time and temperature stated by the manufacturer shall exhibit a similar response at the beginning of the final 30 % of the exposure time.

Compliance shall be tested in accordance with Annex F.

5.2.3 After exposure to dry heat at (140 ± 2) °C for not less than 30 min, the indicator agent shall show either no change or a change that is markedly different from the change occurring after exposure to a steam sterilization process.

Compliance shall be tested in accordance with Annex C.

5.2.4 Transfer of the indicator agent to the material of the standard test pack in which it is intended to be used shall not compromise the result of the test.

Compliance shall be tested in accordance with Annex D.

NOTE Although some transfer can be possible without adversely affecting the performance of the indicator system or test pack, there are currently no test methods available to verify the acceptable limits of indicator agent transfer.

5.2.5 The indicator system shall comply with the requirements of this part of ISO 11140 for the duration of the shelf life specified by the manufacturer.

A documented accelerated ageing procedure may be used in demonstrating compliance.

6 Indicator

6.1 Format

6.1.1 The indicator agent shall be uniformly distributed on its substrate to cover not less than 30 % of the test area of the substrate.

6.1.2 The substrate of the indicator system shall have a uniform ground colour which provides a difference in colour density of not less than 0,3 between ground colour and either the changed or the unchanged indicator agent, as specified by the manufacturer, when the difference in colour density is determined using a reflective densitometer.

Compliance shall be tested in accordance with Annex A.

6.2 Performance

6.2.1 The indicator system shall show a uniform colour change complying with 6.1.2 both after exposure to saturated steam at $(134^{+1,5}_0)$ °C for 3,5 min \pm 5 s and/or exposure to saturated steam at $(121^{+1,5}_0)$ °C for 15 min \pm 5 s, or such other combinations of time and temperature as the manufacturer shall specify for the intended use of product. In all cases, the permitted tolerance on the test temperature shall be $^{+1,5}_0$ °C and the time given shall be the time within which the colour change shall occur.

Compliance shall be tested in accordance with Annex B.

6.2.2 After exposure to conditions used to produce a standard fault condition (see 5.2.2) in the standard test pack as specified in Annex E, the indicator system shall show a non-uniform colour change.

Compliance shall be tested in accordance with Annex F.

6.2.3 After exposure to dry heat at (140 ± 2) °C for not less than 30 min, the indicator agent shall show either no change or a change that is markedly different from the change occurring after exposure to a steam sterilization process. Compliance shall be tested in accordance with Annex C.

6.2.4 Transfer of the indicator agent to the test load shall not compromise the result of the test.

6.2.5 The indicator shall comply with the requirements of this part of ISO 11140 for the duration of the shelf life specified by the manufacturer.

A documented accelerated ageing procedure may be used in demonstrating compliance.

7 Packaging and labelling

7.1 The general requirements in ISO 11140-1 apply.

7.2 In addition, each indicator, indicator system and its packaging shall be clearly marked with the following.

AIR REMOVAL

8 Quality assurance

The general requirements in ISO 11140-1 apply.

9 Sampling conditioning

Test samples shall be conditioned for at least 1 h immediately prior to testing in an environment between (23 ± 7) °C with a relative humidity of 30 % to 70 %.

Annex A (normative)

Determination of the degree of contrast between the colour of the substrate and the indicator agent

A.1 Apparatus

A.1.1 Steam exposure apparatus, as specified in Annex G.

A.1.2 Reflective densitometer, as specified in ISO 5-4, which has been calibrated and the calibration traceable to a national standard.

A.1.3 Standard test pack, as specified in Annex E and chosen by the manufacturer.

A.2 Method

A.2.1 To determine the degree of contrast between the substrate and the changed indicator agent, the indicator is placed in the centre of a test pack and exposed to a cycle of the steam exposure apparatus at the specified operating temperature required for the indicator to produce uniform colour change.

A.2.2 The difference in colour density between the ground colour of the substrate and that of the changed and/or unchanged indicator agent shall be determined on at least three pairs of locations on the indicator, using a reflective densitometer. Paired readings shall be taken equidistantly over the indicator.

A.2.3 This test shall be repeated five times for each of three separate production batches of the indicator.

Annex B (normative)

Method of determining uniform colour change on exposure to saturated steam

B.1 Apparatus

B.1.1 Steam exposure apparatus, as specified in Annex G, where the empty chamber includes chamber furniture.

B.1.2 Temperature sensors, either Class A platinum resistance thermometers as specified in IEC 60751 or tolerance Class 1 thermocouples as specified in IEC 60584-2.

B.1.3 Temperature-recording equipment, with a limit of error of 0,5 °C.

B.1.4 Standard test pack, as specified in Annex E.

B.2 Air removal indicator system

B.2.1 In an otherwise empty chamber, the standard test pack as described in Annex E, with temperature sensors and the indicator system under test inserted in the geometric centre of the pack, shall be exposed to a cycle of the exposure apparatus at the specified operating temperature (see 5.2.1) and the temperatures recorded. When the temperature measured in the drain of the exposure apparatus has attained the set saturated steam temperature, the difference between the measured temperature in the drain of the steam exposure apparatus and in the centre of the test pack shall be less than 0,5 °C and shall remain so for the duration of the exposure time exclusive of a 15 s equilibration time. At the completion of the cycle, the indicator system shall be removed from the standard test pack and examined for compliance with 5.2.1.

B.2.2 This test shall be repeated five times for each of three separate production batches of the indicator and indicator system.

B.3 Air removal indicator

B.3.1 The air removal indicator to be tested shall be placed in an otherwise empty chamber. A temperature sensor shall be placed in the chamber drain of the exposure apparatus. A cycle with the conditions outlined in B.2.1 shall be run. At the completion of the cycle, the indicator shall be removed from the system and examined for compliance with 6.2.1.

B.3.2 The test programme shall consist of:

- a) two replicate cycles complying with 5.2.1, using a standard test pack (Annex E) having temperature sensors in place;
- b) three sets of test cycles complying with 5.2.1, alternating the standard test pack (Annex E) having temperature sensors in place with the air removal indicator.

Annex C (normative)

Method for determining indicator colour change on exposure to dry heat

C.1 Apparatus

C.1.1 Sample holder, as specified by the manufacturer.

C.1.2 Dry heat oven, capable of maintaining a steady temperature of (140 ± 2) °C.

The humidity in the oven should be less than 5 % relative humidity throughout the period of the test. A sample holder may be necessary. Advice should be sought from the manufacturer.

C.2 Air removal indicator system

C.2.1 The oven shall be preheated to the operating temperature.

C.2.2 The test samples shall be placed in the oven and subjected to dry heat at (140 ± 2) °C for (30 ± 1) min. The samples shall be removed and examined for colour change in accordance with 5.2.3.

C.2.3 This test shall be repeated five times for each of three separate production batches of the air removal indicator system. Several test samples may be exposed simultaneously.

C.3 Air removal indicator

C.3.1 The oven shall be preheated to the operating temperature.

C.3.2 The indicator in the air removal indicator system shall be fitted with a temperature sensor to monitor the temperature at the indicator system and be subjected to dry heat at (140 ± 2) °C to determine the time required for the indicator to obtain 135 °C (the heat-up time).

C.3.3 The air removal indicator shall be subjected to dry heat at (140 ± 2) °C for the heat-up time plus (30 ± 1) min. The indicator system shall be removed and examined for colour change in accordance with 6.2.3.

C.3.4 This test shall be repeated five times for each of three separate production batches of the air removal indicator. Several test samples may be exposed simultaneously.

Annex D
(normative)

Method for determining transfer of indicator agent to standard test pack

D.1 Apparatus

D.1.1 Rigid plate, (e.g. acetal, polycarbonate, polysulfone) approximately 200 mm × 100 mm × 5 mm nominal thickness covered with the standard test pack material as specified in Annex E.

D.1.2 Steam exposure apparatus, as specified in Annex G.

D.2 Method

D.2.1 The indicator system shall be centred on the material-covered plate with the indicator agent uppermost. A second piece of material shall be placed on the indicator system and secured by taping along all sides to ensure intimate contact with the indicator agent.

D.2.2 The assembly shall be placed horizontally with the plate as the lowest layer in the steam exposure apparatus and subjected to dry saturated steam at $(134 \pm 1) ^\circ\text{C}$ for 3,5 min and/or $(121 \pm 1) ^\circ\text{C}$ for 15 min.

D.2.3 The indicator system shall be removed and examined for non-uniform colour change due to transfer of indicator agent to standard test pack material in accordance with 5.2.4.

D.2.4 This test shall be repeated five times for three separate production batches.

Annex E (normative)

Standard test pack

E.1 The standard test pack consists of folded 100 % cotton surgical towels. They shall be freshly laundered, but not ironed.

E.2 The towels shall be folded to a size $250 \text{ mm} \pm 20 \text{ mm}$ in one direction and $300 \text{ mm} \pm 20 \text{ mm}$ in the other direction and placed one above the other.

E.3 The height of the test pack shall be between 250 mm and 280 mm.

The total number of towels may vary from test to test, depending on towel thickness and wear.

E.4 The mass of the pack shall be $4 \pm 0,2 \text{ kg}$.

E.5 A single two-ply fabric wrap, made of 100 % cotton with a thread count both warp and weft of 5,5/mm, shall be loosely applied to wrap the test pack.

E.6 The pack shall be secured with tape not exceeding 25 mm in width.

Annex F (normative)

Method of determining non-uniform colour change on exposure to a standard fault condition

F.1 Apparatus

F.1.1 Steam exposure apparatus, as specified in Annex G.

F.1.2 Temperature sensors, either Class A platinum resistance thermometers as specified in IEC 60751 tolerances or Class 1 thermocouples as specified in IEC 60584-2.

F.1.3 Temperature-measuring equipment, with a limit of error of 0,5 °C.

F.1.4 Standard test pack, as specified in Annex E.

F.2 Air removal indicator system

F.2.1 Introduce the two temperature sensor leads into the sterilizer chamber through an entry connection.

F.2.2 One sensor shall be positioned in the geometric centre of the standard test pack and separated from the indicator system by one layer of material. Care shall be taken to prevent the sensor lead from providing a channel for air entry into the test pack. The second sensor shall be placed in the chamber drain at a minimum depth of 10 mm. Care shall be taken not to allow the sensor to come in contact with any surface in the drain.

F.2.3 The test load shall be placed horizontally on the bottom shelf of the chamber furniture, over the drain in an otherwise empty chamber.

F.2.4 The standard test pack, with temperature sensors and the indicator system properly located, shall be exposed to a cycle of the exposure apparatus with a standard fault condition as described in 5.2.2. Record the temperature at each temperature sensor.

F.2.5 At the completion of the cycle, the indicator system shall be removed from the test load and examined for compliance with 5.2.2.

F.2.6 This test shall be repeated five times for each of three separate production batches.

F.3 Air removal indicator

F.3.1 The air removal indicator, with a temperature sensor in the chamber drain of the exposure apparatus, shall be exposed to a cycle with the same conditions as those outlined in F.2.4.

F.3.2 At the completion of the cycle, the indicator system shall be removed from the air removal indicator and examined for compliance with 5.2.2.

F.3.3 The test programme shall consist of:

- a) two replicate cycles, using a standard test pack (see Annex E) having temperature sensors in place and a cycle complying with 5.2.2;
- b) three sets of test cycles complying with 5.2.2, alternating the standard test pack (Annex E) with temperature sensors in place, with the air removal indicator.

Annex G (normative)

Steam exposure apparatus

G.1 General

The steam exposure apparatus shall be a pre-vacuum steam sterilizer for use in health care facilities for wrapped goods and porous loads, and have a chamber volume between 54 l and 800 l. It shall comply with the additional requirements for cycle control specified in this annex. The control system shall allow the simulation of the porous load sterilization cycles currently operated on different machines, and the creation of a standard fault condition. These cycles shall have a high level of reproducibility on replicate runs.

G.2 Instrumentation

G.2.1 Chamber temperature

G.2.1.1 The steam exposure apparatus shall be equipped with a means of continuous readout of chamber temperature with a frequency of at least one measurement every 2 s throughout the cycle. The readout and recording means may be one and the same.

G.2.1.2 The sensor(s) for the readout and recorder shall be so positioned that the temperature measured is representative of the actual chamber conditions.

G.2.1.3 When tested against certified laboratory standards, the temperature readout and recorder shall be accurate to within $\pm 0,5$ °C over the sterilizer's designated operating range.

G.2.1.4 Temperature graduations on the recorder chart shall not exceed 1 °C within a range of ± 5 °C of the set operating temperature.

G.2.2 Pressure

G.2.2.1 The steam exposure apparatus shall be equipped with a readout (mechanical, digital or other device) for indicating the vacuum and the pressure within the chamber. The readout shall be accurate to within ± 3 % of full scale value. The readout shall have graduations or a resolution of 10 kPa or less.

G.2.2.2 When a steam jacket is fitted, the steam exposure apparatus shall be equipped with a readout that displays jacket pressure. The accuracy of a readout shall be within ± 3 % of full scale value, and each graduation or increment of resolution shall be 10 kPa or less.

G.2.3 Timer

G.2.3.1 The steam exposure apparatus shall be equipped with a resettable timer for timing exposure.

G.2.3.2 The timer shall have a minimum accuracy of ± 1 % of the set value.

G.2.4 Sterilizer control systems

G.2.4.1 The control system shall control the chamber temperature to within ${}^+_0$ °C of the set temperature.

G.2.4.2 The mechanism used by the operator to set the operating temperature shall be marked in, or adjustable to, increments no larger than 1 °C within a range of 110 °C to 140 °C.

Bibliography

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- [4] ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*
- [5] ISO 17665-2, *Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ISO 17665-1*

Acknowledgements

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