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Technical requirements for large steam sterilizers — Automatic type

(Version Submitted for Approval)

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Issued by　**General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China (AQSIQ)**

Contents

Introduction

The contents of this Standard are all mandatory.

This Standard replaces four standards, namely GB 8599-88 “Technical conditions of automatic pressure steam sterilizers,” GB 8600-88 “Inspection methods for sterilisation effects of pressure steam sterilizers,” YY 0085.1-92 “Pulse vacuum pressure steam sterilizers,” and YY 0085.2-92 “Pre-vacuum pressure steam sterilizers.” As from the enforcement date of this Standard, the above four standards shall be abolished.

The consistency of this Standard with EN 285: 2006 “Sterilisation — Steam sterilizers — Large sterilizers) is non-equivalent.

Compared with EN 285: 2006, the major changes of this Standard are as follows:

1. Part of the terms and definitions have been deleted. The generally used terms and definitions adopt the terms and definitions determined in GB/T 19971-2005 “Sterilisation of health care products — Vocabulary” and GB 18281.1-2000 “Sterilisation of health care products — Biological indicators — Part 1: General Rules.”
2. The editing and format of this Standard are in accordance with the regulations of GB/T 1.1-2000 “Directives for standardisation — Part 1: Rules for the structure and drafting of standards” and GB/T 1.2-2002 “Directives for standardisation — Part 2: Methodology for the content of normative technical elements in standards.” These Directives have a greater difference from those of EN 285: 2006. Part of the European languages is deleted.
3. Part of the content of pressure vessels is according to the requirements of GB 150-1998 “Steel pressure vessels,” “Supervision Regulations on Safety Technology for Pressure Vessels” formulated by the National Quality and Technical Supervision Bureau (1999), and Directive (No. 373) of State Council of the People’s Republic of China “Regulations on Safety Supervision of Special Equipment.” The Standard is added with the requirements of pressure vessels and the safe interlock requirements of sterilizer doors.
4. In respect to electrical safety requirements, these standards are implemented: GB 4793.1 “Safety requirements for electrical equipment for measurement, control and laboratory use — Part 1: General requirements,” GB 4793.4 “Safety requirements for electrical equipment for measurement, control and

laboratory use — Particular requirements for autoclaves using steam for the treatment of medical materials and for laboratory process" and GB/T 18268-2000 "Electrical equipment for measurement, control and laboratory use — Electromagnetic Compatibility (EMC) requirements" (idt. IEC 61326-1: 1997).

5. The requirements of biological indicators should meet the standards of ISO 11138 series. The requirements of chemical indicators should meet the standards of ISO 11140 series.
6. According to EN 285: 2006 (revised version), the test requirements of hollow load are increased.
7. This Standard does not adopt Chapter 22 "Test of the mass of steam gas source" of EN 285: 2006 (revised version).

Appendix E and Appendix F to this Standard are normative appendices.

Appendix A, Appendix B, Appendix C, Appendix D and Appendix G are informative appendices.

This Standard was proposed by the State Food and Drug Administration.

This Standard is under the jurisdiction of the National Technical Committee for Standardisation of Sterilisation Techniques and Equipment (SAC/TC200).

The drafting units of this Standard are the Guangzhou Medical Equipment Quality Supervision and the Inspection Centre of State Food and Drug Administration, Gietinge Shanghai Trading Co., Ltd., Shandong Xinhua Medical Instruments Co., Ltd., and Lianyuangang Sehoh Medical Equipment Co., Ltd.

The main drafters of this Standard are Huang Shiulian, Xu Weixiong, Wu Qiming, Chen Jiahua, Lu Zifen, Zhang Yang, Li Jing, Wang Peijing and Han Shaochuan.

The National Technical Committee for Standardisation of Sterilisation Techniques and Equipment shall be responsible for the interpretation of this Standard.

Technical requirements for large steam sterilizers — Automatic type

1 Scope

This standard specifies the terms, definitions, types, basic parameters, requirements and test methods for automatic-type large steam sterilizers.

This standard applies to large steam sterilizers available to load one or more sterilising units, and with a capacity larger than or equal to 60 litres (hereinafter referred to as “sterilizers”). The sterilizers are mainly used for the sterilisation of health care products and their accessories.

The sterilizers designed and produced according to this Standard should consider the effects of environmental factors on the durability cycle of products. The environmental factors are shown in Appendix A.

This Standard is not restricted to the application to the requirements of the mass guarantee system that controls the various manufacturing and production stages of sterilizers.

This standard does not apply to manual large steam sterilizers.

2 Normative references

The provisions of the following documents become provisions of this Standard after being referenced. For dated reference documents, all later amendments (excluding corrigenda) and versions do not apply to this Standard; however, the parties to the agreement are encouraged to study whether the latest versions of these documents are applicable. For undated reference documents, the latest versions apply to this Standard.

GB 150 Steel Pressure Vessels

GB 4793.1 Safety requirements for electrical equipment for measurement, control and laboratory use — Part 1: General requirements

GB 4793.4 Safety requirements for electrical equipment for measurement, control and laboratory use — Particular requirements for autoclaves using steam for the treatment of medical materials and for laboratory processes

GB/T 16839.2-1997 Thermocouples — Part 2: Tolerances (idt. IEC 60584-2: 1982+A1: 1989)

GB/T 18268-2000 Electrical equipment for measurement, control and laboratory use — Electromagnetic compatibility (EMC) requirements (idt. IEC

61326-1: 1997)

GB 18281.1-2000 Sterilisation of health care products — Biological indicators — Part 1: General rules (idt. ISO 11138-1: 1994)

GB 18281.3-2000 Sterilisation of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilisation (idt. ISO 11138-3: 1994)

GB 18282.1-2000 Sterilisation of health care products — Chemical indicators — Part 1: General requirements (idt. ISO 11140-1: 1995)

GB/T 19633 Packaging for terminally sterilised medical devices (idt. ISO 11607: 2003)

GB/T 19971-2005 Sterilisation of healthcare products — Vocabulary (idt. ISO/TS 11139: 2001)

JB/T 8622-1997 Technical conditions and index of platinum thermal resistance in Industry (neq. IEC 60751: 1983)

Regulations on Safety Supervision of Special Equipment — Directive (No. 373) of the State Council of the People's Republic of China

Supervision Regulations on Safety Technology for Pressure Vessels formulated by the National Quality and Technical Supervision Bureau (1999)

IEC 60038 IEC Standard voltage

ISO 11140-3: 2000 Sterilisation of health care products — Chemical indicators — Part 3: Class 2 indicators for steam penetration test sheets

ISO 11140-4: 2006 Sterilisation of health care products — Chemical indicators — Part 4: Class 2 indicators as an alternative to the Bowie and Dick Type test for detection of steam penetration

EN 867-5: 2001 Non-biological systems for use in sterilizers — Part 5: Specification for indicator systems and process challenge devices (PCD) for use in performance testing for small sterilizers (Type B and Type S)

3 Terms and definitions

The following terms and definitions as well as those established in GB/T 19971-2005 and GB 18281.1-2000 are applicable to this Standard.

3.1 Air removal

Removing air from the sterilisation chamber and sterilisation pack to enhance steam penetration.

3.2 Automatic controller

A device that controls sterilizer according to the preset parameters to run automatically by following the procedures.

3.3 Bowie and Dick Type test

A test to determine whether the sterilizer available for sterilisation of multiple-hole loads can successfully remove air.

3.4 Cycle complete

It shows that the sterilisation cycle set by the program has been completed, so the sterilised load can be removed from the sterilisation chamber.

3.5 Double ended sterilizer

A sterilizer with a door at each of the two ends of the sterilisation chamber.

3.6 Equilibration time

The time required from the moment the reference measurement point has reached sterilisation temperature, to the moment the various parts of the load have reached sterilisation temperature.

3.7 Holding time

The time for keeping the temperature of reference measurement point inside sterilization chamber and the temperature of the various parts of load within the sterilization temperature band.

Note: Holding time is closely following equilibration time. The length of time is related to sterilisation temperature.

3.8 Hollow load

An article containing lumen structure. The diameter inside lumen body should not be less than 2mm, and the length of the part of lumen body should not be greater than 1500 times of its inner diameter.

3.9 Loading door

The door of a double-ended sterilizer. Before sterilisation begins, a sterilizer load must pass through it in order to be placed in the sterilisation chamber.

3.10 Plateau period

The sum of equilibration time and holding time.

3.11 Pressure vessel

The vessel that includes the sterilisation chamber, jacket (if applicable), door and all other related parts permanently connected to the sterilisation chamber.

3.12 Process challenge device (PCD)

A device forming specific resistance in the sterilisation process. It is used to evaluate the effectiveness of the sterilisation process.

3.13 Reference measurement point

Position of the temperature sensor for controlling the sterilisation cycle.

3.14 Sterilisation module

Sterilizer load at standard volume.

Note: A rectangular parallel pipe. 300mm (height) × 600mm (length) × 300mm (width).

3.15 Sterilisation temperature band

Temperature fluctuation range of load and reference measurement point. Its lowest temperature is the sterilisation temperature.

Note: These temperatures are usually in ^{o}C.

3.16 Sterilizer load

The item(s) undergoing sterilisation treatment inside the sterilisation chamber. Simply referred to as 'load' in this Standard.

3.17 Unloading door

The door of the double ended sterilizer. After a sterilisation cycle is complete, the sterilizer load must pass through this door in order to be removed from the sterilisation chamber.

3.18 Useable space

The valid space inside the sterilisation chamber. The space is not limited by fixed parts, and holds the sterilizer load.

Note: Useable space is expressed through the height, width and depth of the sterilisation chamber.

4 Classification and basic parameters

4.1 Classification

Sterilizers can be divided into several types:

a) According to the method of steam supply that is used, sterilizers are divided into two groups: those with built-in steam generators and those with independent steam generators.

b) There are two types of sterilizer structure: a single ended sterilizer and a double ended sterilizer.

Note: Please refer to Appendix B, "Identification standard of sterilizers of the same module."

4.2 Basic parameters

4.2.1 The rated operating pressure should not be greater than 0.25MPa.

4.2.2 Operating temperature of sterilisation: 115^{o}C ~ 138^{o}C

5 Requirements

5.1 Normal operating conditions

5.1.1 The normal operation of the sterilizer should satisfy the following conditions:

a) Ambient temperature: 5^{o}C - 40^{o}C;

b) Relative humidity: no greater than 85%;

c) Atmospheric pressure: 70kPa ~ 106kPa;

d) Voltage: AC 220V ± 22V, 50Hs ± 1Hz; or AC 380V ± 38V, 50Hz ± 1Hz;

e) Pressure of steam source: 0.3MPa ~ 0.6MPa

5.1.2 For the mass of steam and water, please refer to Appendix C.

5.2 Appearance, structure and dimensions of the sterilisation chamber

5.2.1 The sterilizer should be clean and in good condition, without any obvious defects, damage or rust.

5.2.2 The surface of the sterilizer loading accessory must be free of any damage or defects.

5.2.3 The useable space of the sterilisation chamber can hold one or more sterilisation modules.

5.2.4 The type of sterilizer and the dimensions of the sterilisation chamber should meet the requirements specified by the manufacturer.

5.3 Materials

The materials in contact with steam should:

a) be able to resist steam and condensate corrosion;
b) not reduce steam mass;
c) not release toxic substances that will endanger individuals' health or the environment.

Note: Different combinations of materials are suggested in Appendix D.

5.4 Pressure vessels

5.4.1 Outline

5.4.1.1 Pressure vessels should meet the "Regulations on Safety Supervision of Special Equipment," "Supervision Regulations on Safety Technology for Pressure Vessels," and the regulations of GB150.

5.4.1.2 Interlock device

The device should meet the regulations of Clause 49 and Clause 140 of "Supervision Regulations on Safety Technology for Pressure Vessels":

a) The door of the sterilizer should be equipped with a safe interlock device. When the sterilizer is under normal operating conditions, and when the door has not been tightly locked, steam should not be able to enter sterilisation chamber;
b) The sterilizer door must remain locked until the pressure inside the sterilisation chamber has been completely released;
c) The door must also be fitted with an alarm should the scenarios in a) and b) occur.

5.4.1.3 The seal for the sterilization chamber door should be replaceable. It must be possible to check and clean the seal and its contact surface with the door, without having to remove the door.

5.4.1.4 After the sterilisation chamber door has been closed, it should be able to be opened again before the sterilisation cycle starts.

5.4.1.5 During the sterilisation cycle, the sterilisation chamber door must not be able to be opened.

5.4.2 Double ended sterilizer

5.4.2.1 Except for maintenance, the two doors should not be able to be opened simultaneously.

5.4.2.2 Before the sterilisation cycle is complete, the unloading side door should not be able to be opened.

5.4.2.3 After the BD test, hollow load test and vacuum leakage test have been completed, the unloading side door should not be able to be opened.

5.4.2.4 The device for controlling the start of the sterilisation cycle should be installed on the loading side of the sterilizer.

5.4.3 Test connector

5.4.3.1 Pressure connector: On the sterilisation chamber or the pipeline directly connected to the sterilisation chamber, there should be a pressure test connector. The connector should be marked with “PT” (pressure test) and covered by a cap. It should be effectively sealed by an “O” shaped sealing ring or plain cushion seal.

Note: The requirements of pipe thread are shown in G1/2A of GB/T 7307-2001.

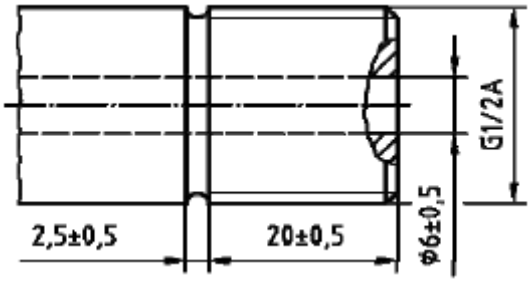


Figure 1 Pressure connector

5.4.3.2 Temperature connector: A temperature test connector, as shown in Figure 2, should be provided. The connector should be installed in a position where maintenance is straightforward, where the soft wire of the temperature sensor can pass through, and where it is easy to connect to all the temperature test points. The connector should be marked with “TT” (temperature test) and covered by a cap. It should be effectively sealed by an “O” shaped sealing ring or plain cushion seal. Heat insulation and mechanical shock absorption cushions should also be installed.

Note: The requirements of pipe thread are shown in G1A of GB/T 7307-2001.

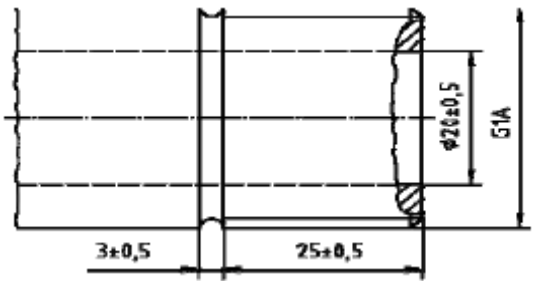


Figure 2 Temperature connector

5.4.3.3 The tee and joint with sealing suppository for testing should be installed in a corresponding way in order to connect with test instruments calibrating the pressure meter that is connected to the sterilisation chamber and jacket (please refer to Subsections 5.6.1.2 and 5.6.1.4).

5.4.4 Heat insulation material

Unless the heat insulation material affects the operation of the sterilizer, the outer surface of the pressure vessel should be heat insulated so as to achieve a minimum of heat loss.

5.5 Sterilizer parts

5.5.1 Pipelines

5.5.1.1 The pipe connector and its device are available in two types: pressure close type and vacuum close type.

5.5.1.2 Unless the normal operation of the sterilizer is compromised, heat insulation measures should be adopted when the temperature of the steam and water pipelines is higher than 60^{o}C, in order to achieve a minimum of heat loss in the environment.

Note: In order to decrease the occurrence of condensation in the pipeline, it is suggested that the cold-water pipeline should be heat insulated.

5.5.1.3 Measures should be taken to control the size and amount of particles entering and affecting the performance of the sterilizer.

Note: Suitable filters may be used.

5.5.1.4 All the control valves on the pipeline should be attached with permanent labels relating to their functions (please refer to Subsection 5.12).

Note: Reference numbers or written descriptions can be used.

5.5.2 Steam source

5.5.2.1 When the sterilizer is in operation, external steam sources can be used to provide steam, or the sterilizer itself can have a built-in steam generator.

5.5.2.2 Sterilizers with a built-in steam generator should meet the following requirements:

a) The steam generator must be installed with a low water level control. When the water level falls below the preset position, the heating element is automatically cut off, and an alarm signal is activated.

b) The pressure output of the steam generator should be stable, and should not exceed the designated pressure. If the pressure output is lower than operating pressure, it should be able to connect with heating power automatically.

5.5.2.3 The in-flow water pipe should be designed to be able to prevent back flow.

5.5.2.4 The power and capacity of the steam generator should meet the application requirements for the sterilizer.

5.5.2.5 The manufacturer should indicate the mass of supply water (please refer to Appendix C).

5.5.3 Air filter

5.5.3.1 When air is required in the sterilisation chamber during a sterilisation cycle, air must first pass through the filter.

Note: The air filter must be made of non-corrosive and non-degrading materials. These materials prolong the lifespan of the sterilizer.

5.5.3.2 The filter should filter out the particles at a diameter of above 0.3 μm, and such filter efficiency should not be lower than 99.5%.

5.5.3.3 The filter should be installed in a position outside the sterilisation chamber, where replacement and maintenance are straightforward, and should be kept dry.

5.5.3.4 Between the filter and the sterilisation chamber, a check valve should be installed to prevent steam from entering the filter.

5.5.4 Vacuum system

A vacuum system is used for air removal and drying. The manufacturer should clearly meet the minimum vacuum degree required in this Standard.

Note: In order to meet the dryness requirement of load, the vacuum system is suggested to be equal to or less than 4kPa.

5.6 Meters —Display and recording devices

5.6.1 Equipment

5.6.1.1 Outline

a) The sterilizer meters should be installed in a place where the operator can check them easily, and should be differentiated according to their different functions;

b) Unless there are special requirements, the readings on meters should be available to be easily read by people with normal eyesight under low environmental illumination (215 ± 15) Lx at a distance of (1.00 ± 0.15)m;

c) The temperature and humidity around the meters should meet the regulations of the meter manufacturer.

Note: Normally, the temperature around the meters should not exceed 50^{o}C, and the relative humidity should not exceed 85%.

5.6.1.2 Meters

A sterilizer should contain at least the following parameters:

a) Temperature indicator for the sterilisation chamber;

b) Temperature recording instrument for the sterilisation chamber;

c) Pressure indicator for the sterilisation chamber;

d) Pressure recording instrument for the sterilisation chamber;

e) Pressure indicator for the sterilizer jacket;

f) If a built-in steam generator is used, there should be a table of steam pressure.

Note 1: In addition to the related requirements of GB4793.4, items a), c), e) and f) can be integrated and displayed in the same system. The displayed contents can be selected by the user.

Note 2: Items b) and d) can be combined.

5.6.1.3 Display device

The display device of the sterilizer should indicate at least the following messages:

a) A visible indication signal, showing that "the door is locked";

b) A visible indication signal, showing that "the cycle is processing";

c) A visible indication signal, showing that "the cycle is completed";

d) A visible indication signal, showing "malfunction" (please refer to Subsection 5.7.2);

e) An indication signal showing the selected sterilisation cycle;

f) Sterilisation cycle counter;

g) An indication signal showing the stage of sterilisation cycle;

Note: Item g) can be used together with items a), b) and c).

The indication signal for completion of a cycle should disappear when the door is open.

5.6.1.4 Double ended sterilizers

The two ends of the sterilizer should at least include:

a) Pressure indicator for the sterilisation chamber;

b) A visible indication signal, showing that "the door is locked";

c) A visible indication signal, showing that "the cycle is processing";

d) A visible indication signal, showing that "the cycle is completed";

e) A visible indication signal, showing "malfunction" (please refer to Subsection 5.7.2).

5.6.2 Sensor, indication meter and timing equipment

5.6.2.1 Temperature

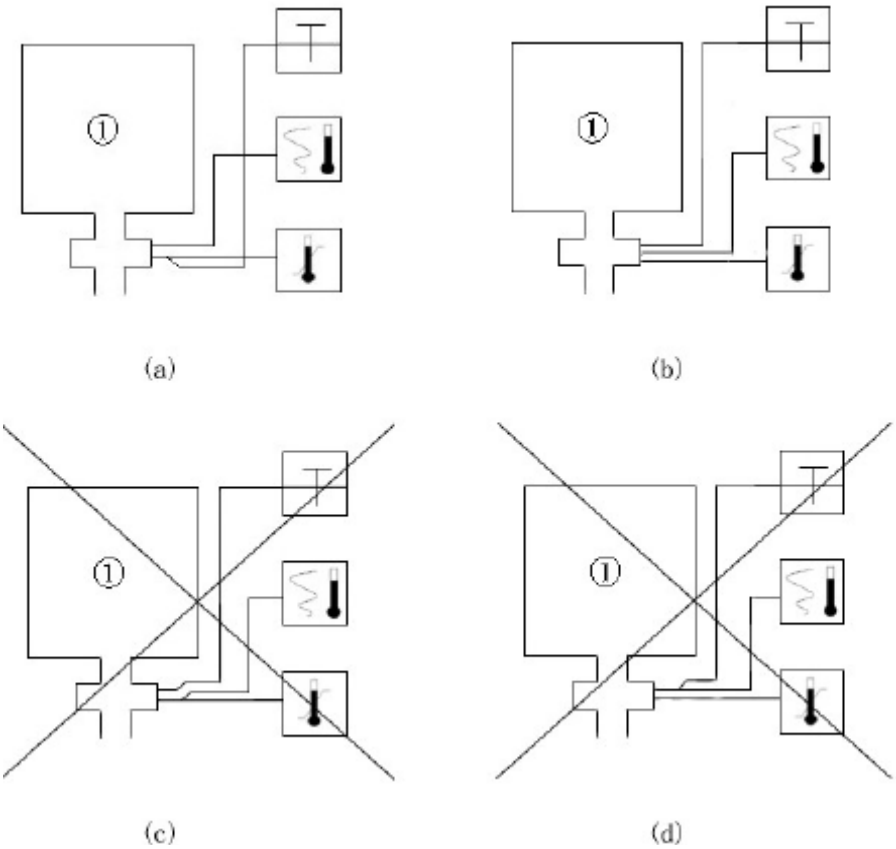
a) Temperature sensor

The temperature sensor should be of platinum resistance type or thermoelectric coupling type with a minimum accuracy of ± 1%.

Note: Other systems with equivalent effects can also be used.

When the test is performed in water, the response time of temperature sensor should be $\tau_{90} \leq 5$s.

At least two independent temperature sensors should be provided. Their recording systems must be attached with independent sensors. These sensors and temperature meter are connected to the sterilizer, as shown in (a) and (b) of Figure 3. The connections in (c) and (d) in Figure 3 are not allowed.



Note: ① Sterilizer

Temperature indication meter for the sterilizer

Temperature recording instrument

Temperature controller during plateau period

Figure 3 Several connection options for the temperature sensor

The indicator for controlling the sterilisation cycle and displaying the temperature of the sterilisation chamber should be placed at the reference measurement point determined by the manufacturer.

b) Moveable temperature sensors should be placed inside the sterilisation chamber (if applicable)

When a moveable temperature sensor and its wire are placed inside the sterilisation chamber, it should be designed to be resistant to high temperature, and adopt pressure, vacuum and steam sealing measures.

c) Temperature indication meter for the sterilisation chamber

The temperature indication meter for the sterilisation chamber should:

— Be either numerical type or simulated type;

— Have a numerical range of 50°C ~ 150°C;

— Have an accuracy of ± 1% minimum within the numerical range of 50°C ~ 150°C;

— For a simulated type meter, each of the divided equal parts of temperature graduation should not be greater than 2°C;

— For a numerical type meter, the resolution should be 0.1°C or better;

— Have an accuracy of ± 0.5°C minimum during the measurement of sterilisation temperature;

— The error compensation of the surrounding environmental temperature should not exceed 0.04°C/°C;

— Under the circumstances that the meter is not separate, there should be standard tools available to make instant adjustments.

5.6.2.2 Pressure

The pressure indication meter for the sterilisation chamber should:

— Meet the regulations of Clause 160 of "Supervision Regulations on Safety Technology for Pressure Vessels";

— Be either numerical type or simulated type;

— Use the pressure unit of kPa or MPa;

— Have a numerical range of (0kPa ~ 400kPa) or (-100kPa ~ 300kPa), with pressure indicating 0 in a situation of absolute vacuum or atmospheric pressure;

— Have an accuracy of ± 1.6% minimum within the numerical range of (0kPa ~ 400kPa) or (-100kPa ~ 300kPa);

— For simulated type meters, each of the divided equal parts of graduation should not be greater than 20kPa;

— For numerical type metres, the resolution should be 1kPa or above;

— Have a minimum accuracy of ± 5kPa during the measurement of operating pressure;

— Be within the numerical range of (0kPa ~ 400kPa) or (-100kPa ~ 300kPa); the error compensation of the surrounding environmental temperature should not exceed 0.04%/°C;

— Under the circumstances that the meter is not separate, there should be standard tools available to make instant adjustments.

5.6.2.3 Time indicator

If a time indicator is installed, it should:

a) Be indexed as hour (h), minute (min) and second (s) according to

application needs;

b) Have an error margin not exceeding ± 1%.

5.6.3 Recording instrument and its record

5.6.3.1 Outline

a) The recording instrument should be of a numerical type or simulated type;

b) The measured and printed numerical values of the recording instrument should be independent to the automatic controller;

c) The record should include the numerical values of all the key transition points of pressure in the entire sterilisation cycle. The printed data should be able to determine that the parameters can reach the preset values, and are within permissible tolerances;

Note: The sampling points of the procedure parameter variation record, which is required to be recorded during a sterilisation cycle, are shown in Table 1 and Figure 4.

d) The data recorded must be made available for a specified length of time, and cannot be altered;

e) Under the illumination conditions of (215 ± 15) Lx, staff with normal eyesight should be able to read the record easily at a distance of (250 ± 25) mm;

f) If time has to be indicated, the units adopted should be second (s), minute (min) or their combination. The accuracy for the length of time within 5 minutes should be ± 2.5% minimum, and for over 5 minutes should be 1% minimum;

g) The recording instrument should be instantly adjustable.

5.6.3.2 Simulated recording instrument

a) Paper speed

The paper speed of the simulated-type recording instrument should not be lower than 4mm/min.

b) Temperature

The simulated-type temperature recording instrument should:

— Use degrees Celsius (^{o}C) as the unit of temperature data in the chart;

— Have a numerical range of 50^{o}C ~ 150^{o}C;

— Have an accuracy of ± 1% minimum within the numerical range of 50^{o}C ~ 150^{o}C;

— Have each of the divided equal parts of temperature graduation in the chart not being greater than 2^{o}C;

— Have a resolution of 1^{o}C or better;

— Have an accuracy of ± 1^{o}C minimum during the measurement of sterilisation temperature;

— Have a sampling cycle of no more than 2.5s for each sampling channel.

c) Pressure

The simulated-type pressure recording instrument should:

— Use kPa or MPa as the unit of pressure data in the chart;

— Have a numerical range of (0kPa ~ 400kPa) or (-100kPa ~ 300kPa), with pressure indicating 0 in a situation of absolute vacuum or atmospheric pressure;

— Have an accuracy of ± 1.6% minimum within the numerical range of (0kPa ~ 400kPa) or (−100kPa ~ 300kPa);

— The numerical division of pressure in the chart should not be greater than 20kPa;

— Have a resolution of 5kPa or better;

— Have an accuracy of 5kPa minimum during the measurement of operating pressure;

— Have a sampling cycle of no more than 2.5 seconds for each sampling channel.

5.6.3.3 Numerical recording instrument

a) Temperature

The temperature recording instrument producing numerical records:

— Is able to record text;

— Has a numerical range of 50^{o}C ~ 150^{o}C;

— Has a resolution of 0.1^{o}C or better;

— Has an accuracy of ± 1% minimum within the numerical range of 50^{o}C ~ 150^{o}C;

— Has a paper width of no fewer than 15 characters / line;

— Has a sampling cycle of no more than 2.5 seconds for each sampling channel.

b) Pressure

The pressure recording instrument producing numerical records:

— Is able to record text;

— Has a numerical range of (0kPa ~ 400kPa) or (-100kPa ~ 300kPa);

— Has a resolution of 1kPa or better;

— Has an accuracy of ± 1.6% minimum within the numerical range of (0kPa ~ 400kPa) or (-100kPa ~ 300kPa);

— Has a paper width of no fewer than 15 characters / line;

— Has a sampling cycle of no more than 1second for each sampling channel.

Table 1 Examples of numerical values to be recorded

Procedure	Time	Temperature	Pressure	Sterilisation (1)		Date (1) and Identification of Sterilizer
		(Measured Value)		Cycle Identification	Counter No.	
Electrified	✓	—	—	—	—	✓
Started	✓	—	—	✓	✓	✓
t_i	✓	—	✓ (2)	—	—	—
t_{i+1}	✓	—	✓ (2)	—	—	—
t_j	✓	✓	✓	—	—	—
t_{j+1}	✓	✓	✓	—	—	—
t_{j+2}	✓	—	✓	—	—	—
t_{j+3}	✓	—	✓	—	—	—
Completed	✓	—	—	—	—	—
Power Off	✓	—	—	—	—	—

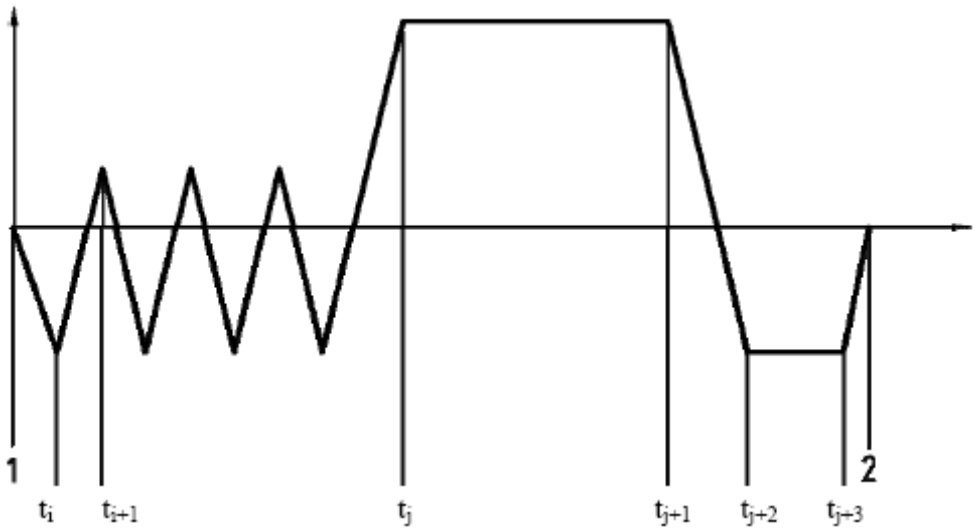
Note 1: "(1)" indicates that the simulated recording system is a selective item; "(2)" indicates that each pressure transition is recorded.

Note 2: t_i — Commencement time of steam injection for the i^{th} time; t_{i+1} — Commencement time of pulse vacuum for the $i+1^{th}$ time;

t_j — Commencement time of plateau period; t_{i+1} — Completion time of holding time;

t_{i+2} — Commencement time of drying period; t_{i+3} — Completion time of drying period.

Note 3: "✓" indicates that the record has to be kept; and "—" indicates that the record is not required to be kept.



Note: 1 — Commencement

2 — Completion

Figure 4 Schematic diagram of sterilisation cycle

5.7 Control system

5.7.1 Outline

5.7.1.1 The automatic control system of the sterilizer should be able to have one or several preset sterilisation cycles.

5.7.1.2 The key parameters of sterilisation technology specified by the manufacturer should be able to reappear within the range specified in Subsection 5.7.1.3.

5.7.1.3 The manufacturer should specify the program control parameters and tolerance of the automatic controller to ensure that they meet the requirements of Subsection 5.8.3.

5.7.1.4 The manufacturer should determine:

a) That at the sterilisation stage, the temperature of the selected reference measurement point is clearly related to the temperature of the sterilisation chamber useable space;

b) The relationship between the temperature of the selected reference measurement point and the lowest temperature point of the sterilisation chamber useable space.

5.7.1.5 In the case of a malfunction in the automatic controller, there should be a safety device that safely returns the pressure inside the sterilisation chamber to the status of atmospheric pressure, and allows the loading door to open.

5.7.1.6 The sterilisation chamber temperature indication instrument and pressure indication instrument should be equipped with a fault protection sensor (please refer to Subsection 5.7.2.4).

5.7.1.7 The error margin of any timer used for controlling time intervals should not exceed 1% of the specified value.

5.7.1.8 The adjustment of control devices should only be performed with standard tools.

5.7.1.9 For routine maintenance, test and emergency needs, manual setting procedures should be provided. Manual operation should be performed using standard tools. This should be different from the specification in Subsection 5.7.1.8.

The selected manual operation model should be available to be displayed.

5.7.1.10 Sterilizers should be attached with a protective device to prevent the input and output circuits connecting with the automatic controller and creating a short-circuit.

5.7.1.11 The control system should indicate the input and output statuses.

Note: These indication devices can be installed inside the control box.

5.7.1.12 Make sure that under testing and normal operating conditions, when the parameters of system specified in Subsection 5.7.1.3 cannot be reached, the system is able to display that there is a malfunction.

5.7.1.13 If the holding time specified for the indicators used for determining the steam penetration effect is different from the plateau period used in the regular sterilisation cycle, then an independent test cycle should be performed. The cycle should have the same air removal stage as the routine sterilisation cycle.

5.7.1.14 The automatic test procedures for vacuum leakage should be provided. Within the pressure range in the entire test process, whenever the pressure rises for 1.5kPa, the measurement error should not exceed 0.1kPa.

5.7.1.15 When a test cycle is running, the display upon completion should be different from that of a routine sterilisation cycle.

5.7.2 Malfunction display system

5.7.2.1 If the cycle parameter variation value exceeds the limited value specified by manufacturer (please refer to Subsection 5.7.1.3), or the medium supply fault is great enough to affect the satisfaction of these variation requirements, or leads to the suspended running of equipment, the automatic controller should:

a) Provide a visible malfunction indication;

Note: In addition, it is proposed that an alarm device with higher sensitivity should be provided.

b) Display the current cycle stage.

5.7.2.2 If the sterilizer is installed with a printer, the malfunction messages should be able to be printed.

5.7.2.3 After the malfunction message is displayed, the visible display of such malfunction should be kept on screen at least until the door’s interlock device is

opened by the staff using standard tools.

Note: It should be noted whether or not the sterilizer load has been sterilised.

5.7.2.4 When the sensor shows an open-circuit fault, the system should provide a malfunction indication.

5.8 Performance requirements

5.8.1 Steam penetration

5.8.1.1 BD test (not applicable to lower-exhaust-type sterilizers)

Sterilizers should perform this test according to the regulations of Subsection 6.8.1.1. The discolouration of indicators in the entire BD test should be even.

5.8.1.2 Hollow load test (not applicable to lower-exhaust-type sterilizers)

Sterilizers should perform this test according to the regulations of Subsection 6.8.1.2. The discolouration of chemical indicators should be able to reach the final point specified by manufacturer.

Note: Each steam sterilization process is independent. Regular steam penetration tests can provide very important information. Measures should be taken to ensure that there is sufficient steam penetration in each cycle.

5.8.2 Sterilisation effect of resin load

Perform the test according to the regulations of Subsection 6.8.2. Cultivation should be made according to the regulations specified by the manufacturer of the biological indicators. During the sterilisation cycle, the exposed biological indicators no longer have biological activity. When the untreated biological indicators are cultivated under the same conditions, they then possess biological activity.

Note: The requirements of biological indicators are shown in GB 18281.3-2000.

5.8.3 Temperature parameters

5.8.3.1 Sterilisation temperature band

The lower limit of the sterilisation temperature band is sterilisation temperature, and the upper limit is sterilisation temperature + 3^{o}C.

5.8.3.2 Small-load temperature

a) For sterilizers with a sterilisation chamber capacity of no more than 800L, the equilibration time should not exceed 15 seconds. For sterilizers with greater capacity, the equilibration time should not exceed 30 seconds.

b) During the plateau period, the temperature acquired at the upper measurement point of the standard test pack should not be more than 5^{o}C higher than the temperature tested at the reference measurement point of sterilisation chamber within the first 60 seconds. After 60 seconds, the temperature should not be more than 2^{o}C higher.

c) During the holding time, the temperature tested at the reference measurement point of the sterilisation chamber, the temperature of any

single test point in the standard test pack, and the saturated steam temperature checked according to the pressure of sterilisation chamber should meet the following requirements:

— They should be within the sterilisation temperature band;

— The difference between the various points should not exceed 2°C (please refer to Figure E.1).

d) For sterilizers with a sterilisation temperature of either 121°C, 126°C or 134°C, the holding time should not be less than 15 minutes, 10 minutes and 3 minutes respectively.

Note: Other temperature and time combinations are applicable.

5.8.3.3 Temperature of full load

a) For sterilizers with a sterilisation chamber capacity of no more than 800L, the equilibration time should not exceed 15 seconds. For sterilizers with greater capacity, the equilibration time should not exceed 30 seconds.

b) Upon completion of equilibration time, the temperature tested at the reference measurement point of the sterilisation chamber, as well as the temperatures measured at the geometric centre of the standard test pack and beneath the top cotton cloth layer inside the pack (please refer to Subsection F.1) should be within the sterilisation temperature band.

c) During the holding time, the temperature tested at the reference measurement point of the sterilisation chamber, the temperature of any single test point in the test pack, and the saturated steam temperature calculated according to the pressure of sterilisation chamber should meet the following requirements:

— They should be within the sterilisation temperature band;

— The difference between the various points should not exceed 2°C (please refer to Figure E.1).

d) For sterilizers with a sterilisation temperature of 121°C, 126°C or 134°C, the holding time should not be less than 15 minutes, 10 minutes and 3 minutes respectively.

Note: Other combinations of temperature and time are applicable.

5.8.3.4 Vacuum leakage

Sterilizers should perform this test according to the regulations of Subsection 6.8.3.4. The speed of any pressure rise should not exceed 0.13kPa/min.

5.8.4 Dryness of load

5.8.4.1 Dryness of fabric in small loads

Sterilizers should perform this test according to the regulations of Subsection 6.8.4.1. The mass increase of the test sample should not exceed 1%.

5.8.4.2 Dryness of fabric in full loads

Sterilizers should perform this test according to the regulations of Subsection 6.8.4.2. The mass increase of the test sample should not exceed 1%.

5.8.4.3 Dryness in metal loads

Sterilizers should perform this test according to the regulations of Subsection 6.8.4.3. The mass increase of the test sample should not exceed 0.2%.

5.9 Noise

When sterilizers are running normally in the sterilisation cycle, there should be no abnormal sound, and the noise should not be greater than 85dB (weighted noise A).

5.10 Pressure change rate

Perform this test according to the regulations of Subsection 6.10. In the sterilisation cycle process, the average pressure change in any interval of 3 seconds should not exceed 1000kPa/min.

5.11 Safety requirements

5.11.1 The electrical safety of the appliance should meet the requirements of GB 4793.1 and GB 4793.4.

5.11.2 The electromagnetic compatibility of the appliance should meet the requirements of GB/T 18268-2000.

5.12 Labelling

Apart from meeting the requirements specified in GB 4793.1 and GB 4793.4, as a minimum, there should be permanently and firmly affixed labels with clear and legible information as follows:

— Manufacturing / supplying unit;

— Registration number of product;

— Model number;

— Production date or number;

— Description stating that the sterilizer is “a steam sterilizer applicable to the packaging of items and multiple-hole loads”;

— Control valve functions (please refer to Subsection 5.5.1.4).

6 Test methods

6.1 Test conditions

Perform the tests under normal operation conditions according to the regulations of Subsection 5.1.

6.2 Tests of appearance, structure and sterilisation chamber’s dimensions

Perform a visual check. According to the manufacturer’s documents and figures, which are approved based on the specified procedures, the dimensions of the sterilisation chamber should be measured, and should meet the requirements of

Subsection 5.2.

6.3 Material test

Refer to the certificate provided by the manufacturer that details material that is in contact with the sterilizer and steam. It should meet the requirements of Subsection 5.3.

6.4 Pressure vessel test

6.4.1 Refer to the manufacturer's product plate and product quality certificate respectively registered at and issued by the boiler pressure vessel safety supervision authority. Visually check, operate and inspect the pressure vessel, which should meet the requirements of Subsection 5.4.1.

6.4.2 Double ended sterilizer test

Operate and check. It should meet the requirements of Subsection 5.4.2.

6.4.3 Test of test connector

Operate and use general measuring tools to check it. It should meet the requirements of Subsection 5.4.3.

6.4.4 Heat insulation material test

The heat insulation material of sterilizers should be checked according to the requirements specified in the technical manual and documents provided by the manufacturer. It should meet the requirements of Subsection 5.4.4.

Note: If necessary, sterilizers should perform tests under the environmental temperature of (23 ± 2) ^{o}C. Use a numerical thermometer to measure the temperature on the outer surface of the heat insulation material.

6.5 Test of sterilizer parts

6.5.1 Pipeline test

6.5.1.1 Perform the test according to the test methods of Subsection 6.4.4. It should meet the requirements of Subsection 5.5.1.2.

6.5.1.2 Perform an inspection. It should meet the requirements of Subsections 5.5.1.1, 5.5.1.3 and 5.5.1.4.

6.5.2 Steam source test

Operate, and check the technical information. It should meet the requirements of Subsections 5.5.2.

6.5.3 Air filter test

Refer to the quality document or certificate provided by the manufacturer, and operate the inspection. It should meet the requirements of Subsections 5.5.3.

6.5.4 Vacuum system test (if applicable)

Perform the test according to the operation methods specified on the sterilizer user manual provided by the manufacturer, and check the vacuum indication meter. It should meet the requirements of Subsection 5.5.4.

6.6 Meter — Test of display and recording devices

6.6.1 Equipment test

Operate, inspect and visually check the equipment. It should meet the requirements of Subsection 5.6.1.

6.6.2 Sensor, indication meter and timing equipment test

Operate, inspect and visually check the equipment. Refer to the related quality certificates provided by the manufacturer. They should meet the requirements of Subsection 5.6.2.

6.6.3 Testing the recording instrument and its records

Operate, inspect and visually check the instrument. Refer to the related quality certificates provided by the manufacturer. They should meet the requirements of Subsection 5.6.3.

6.7 Control system test

6.7.1 Outline

Operate and check the system according to the operation manual provided by the manufacturer. Refer to the related quality certificate provided by the manufacturer. It should meet the requirements of Subsection 5.7.1.

6.7.2 Test of malfunction display system

Simulate the inspection of a malfunction. It should meet the requirements of Subsection 5.7.2.

6.8 Test of performance requirements

6.8.1 Steam penetration test

6.8.1.1 BD test

A BD test determines whether air removal is successfully performed during the sterilisation of multiple-hole loads by the sterilizer. A successful BD test shows that the test pack has undergone rapid and coherent steam penetration. The reasons for air remaining inside the test pack are as follows:

— The air removal is incomplete;

— Vacuum leakage appears at the stage of air removal;

— Non-condensed gas appears in the process of steam supply.

The above situations would lead to the failure of the test.

The test results may be affected by other factors restricting steam penetration. Therefore, from the failure of a test, it cannot be immediately judged whether the reason is air residue, vacuum leakage or non-condensed gas. Therefore, it must be attempted to decrease the effects caused by other possible factors.

6.8.1.1.1 Equipment requirements

a) The standard test pack that meets the requirements of F.1 is for sterilizers loading more than one sterilisation module. The small-sized test pack that

meets the regulations of F.2 is for sterilizers loading one sterilisation module only.

b) The indicators of the BD test should meet the requirements of ISO11140-3: 2000;

c) The medium pipeline connection should meet the requirements of Subsection 5.5.1.

6.8.1.1.2 Test procedures

a) Select the required sterilisation cycle for the test (please refer to Subsection 5.7.1.13).

b) In cases where there is no load and no additionally extended drying time, a sterilisation cycle is run;

c) Open a standard test pack and place the test indicators on the layer around the central position of the standard test pack. Re-assemble it according to the descriptions of F.1 or F.2, and ensure its safety;

d) Place the standard test pack in the centre of the sterilisation chamber, at a height of 100mm ~ 200mm. For sterilizers that can load a sterilisation module only, the standard test pack should be placed on the bottom of the sterilisation chamber;

e) Start the sterilisation cycle according to the procedures;

f) Check the indicators when the test is ended. They should meet the requirements of Subsection 5.8.1.1.

6.8.1.2 Hollow load test (applicable to the sterilizers that perform hollow load sterilisation)

A hollow load test is used to determine that the degree of air dilution is sufficient to make steam evenly penetrate inside the lumen test body when the preset control parameter has reached the standard.

6.8.1.2.1 Test equipment

a) The hollow load process challenge device (PCD) that meets the requirements of F.10 in Appendix F undergoes pre-treatment, giving the inner and outer surface a temperature of between $20^{o}C$ ~ $30^{o}C$, and a relative humidity of 49% ~ 60%.

b) The hollow load test PCD and its indication system should meet the requirements of Standard EN867-5.

6.8.1.2.2 Test procedures

a) Select the sterilisation cycle required to perform the test (according to the requirements of Subsection 5.7.1.13). Make sure that the plateau period and sterilisation temperature meet the requirements of indication system specified in Subsection 6.8.1.2.1 b);

b) No-load running is performed in the sterilisation cycle. The drying time shall not be extended;

c) Open the pipe cap. According to the manufacturer's explanation, there should be no visible water, and the connecting part of the PCD should be completely sealed.

d) According to the manual regulations, the chemical indicators should be fixed, covered by a pipe cap and sealed;

e) Pack and seal the PCD using the paper-plastic packaging material that meets the requirements of GB/T 19633. Place it in the centre of the sterilisation chamber, and at a height of 100mm ~ 200mm from the bottom;

f) Run a sterilisation cycle;

g) Upon the completion of the test cycle, check whether the changes of chemical indicators meet the requirements of Subsection 5.8.1.2;

h) Handle the used chemical indicators according to the manufacturer's instructions.

6.8.2 Test of sterilisation effect of resin load

6.8.2.1 Test equipments

a) A resin test pack as described in Subsection F.8;

b) Simulate the natural resin product with the maximum load;

c) The dimensions of a certain number of test packs are equivalent to a standard sterilisation module basket;

d) All the biological indicators are produced in the same batch;

e) The medium pipeline connection should meet the requirements of Subsection 5.5.1.

6.8.2.2 Test procedures

a) Perform a leakage test according to the regulations of Subsection 6.8.3.4. If the flow speed of leaked gas exceeds that specified in Subsection 5.8.3.4, the test should be stopped;

b) Select the sterilisation cycle to be tested;

c) Run the sterilisation cycle under no-load conditions;

d) Place the resin test pack in the position that the manufacturer indicates it most difficult to perform sterilisation. Fill the rest of the useable space with the sterilisation baskets, each of which is loaded with around 2.2kg of natural resin product;

e) Run a sterilisation cycle, and perform the following tests:

— Check and record the time, number of pulses, temperature, pressure and vacuum degree of all the important stages of the entire sterilisation cycle, e.g. the transition between sterilisation stages;

— Check and record the temperature and pressure of the sterilisation chamber during the beginning, middle and end of the sterilisation holding stage;

— Make sure that the recording device installed in the sterilizer has recorded the entire sterilisation cycle (please refer to Subsection 5.6.3).

f) Upon completion, the following operations should be run continuously:

— Check whether there is any visible indication showing that the entire test cycle has been completed;

— Cultivate at least 10 biological indicators according to the instruction of the manufacturer of biological indicators. Check whether 9 of the sterilised biological indicators have been deactivated. The remaining unhandled biological indicator should be proved to be activated. The result should meet the requirements of Subsection 5.8.2; otherwise, the test is considered invalid, and a re-test should be performed;

— Check the test record. It should meet the requirements of the sterilisation cycle.

6.8.3 Temperature parameter test

6.8.3.1 Testing the sterilisation temperature band

Perform the test according to the methods indicated in Subsections 6.8.3.2 and **6.8.3.3**. It should meet the requirements of Subsection 5.8.3.1.

6.8.3.2 Small-load temperature test

In the small load temperature, a test pack is used. It is used to prove whether the temperature conditions for sterilisation have been acquired inside the sterilisation chamber and the standard test pack after the air removal stage of the sterilisation cycle.

6.8.3.2.1 Equipment requirements

a) For sterilizers that can load a sterilisation module only, a small-sized test pack indicated in Subsection F.2 should be used. For sterilizers that can load more than one sterilisation module, the standard test pack indicated in F.1 should be used;

b) The temperature and pressure recording equipment is as described in F.5 and F.6;

c) The 7 temperature sensors are as described in F.4;

d) The connecting point between the temperature sensor and the sterilisation chamber should be a G1A pipe thread. It must not affect the vacuum and pressure degree of the sterilisation chamber;

Note: Please refer to G1A pipe thread requirements shown in GB/T 7307-2001.

e) The medium pipeline connection should meet the requirements of

Subsection 5.5.1.

6.8.3.2.2 Test procedures

a) The connector passing through the temperature sensor links the temperature sensor to the sterilisation chamber;

b) Perform the leakage test as described in Subsection 6.8.3.4. If the flow speed of leaked gas exceeds that specified in Subsection 5.8.3.4, the test should be stopped;

c) Place a temperature sensor on the reference measurement point;

d) Select the sterilisation cycle to be tested;

e) Run the sterilisation cycle under no-load conditions;

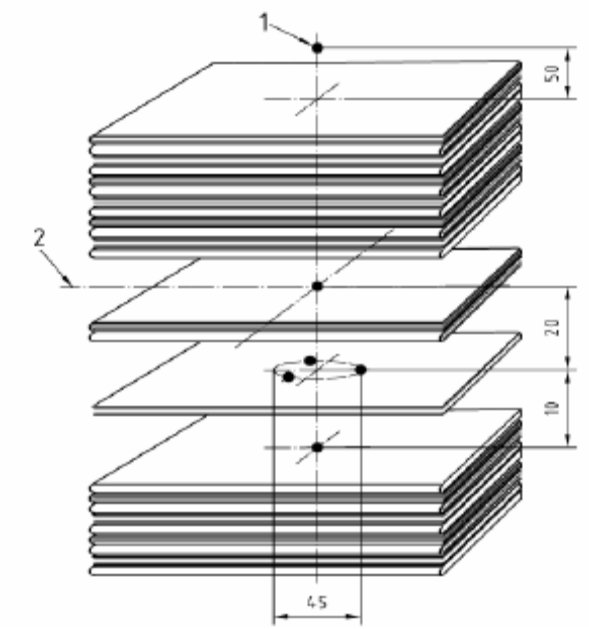
f) Open the package of the standard test pack. Put 5 temperature sensors inside the standard test pack at the positions indicated in Figure 5. If they are the same as described in F.1 or F.2, the test pack should be re-packed;

g) Place the test pack at the centre of the sterilisation chamber, at a height of between 100mm ~ 200mm. For sterilizers that can handle a sterilisation module only, this test method should be revised accordingly that the test pack should be placed on the bottom of the sterilisation chamber;

h) Fix the 7^{th} temperature sensor in the centre, 50mm above the upper surface of the test pack;

i) Run a sterilisation cycle, and perform the following measurements:
   — Check and record the required time, number of pulses, temperature, pressure and vacuum degree of the various important stages of the entire sterilisation cycle, e.g. the transition between sterilisation stages;
   — Check and record the temperature and pressure of the sterilisation chamber during the beginning, middle and end of the sterilisation holding stage;
   — Make sure that the recording device installed in the sterilizer has recorded the entire sterilisation cycle (please refer to Subsection 5.6.3);

j) Upon test completion, the following operations should be run continuously:
   — Check whether there is any visible indication showing that the entire test cycle has been completed;
   — Check the test record. It should meet the requirements specified in Subsection 5.8.3.2;
   — Check the test record. It should meet the requirements of sterilisation cycle.



1 — position of sensor

2 — central layer

Figure 5 Position of sensor

6.8.3.3 Temperature test in times of full load

The full-load temperature test uses the loadable mass of the maximum load specified by the manufacturer. The test load should fill up the entire useable space in the sterilisation chamber. It is used to assess whether the temperature conditions for sterilisation, as specified by the manufacturer, have been reached.

6.8.3.3.1 Equipment requirements

a) The full-load fabrics are as described in Subsection F.7;

b) The temperature and pressure recording equipment is as described in Subsections F.5 and F.6.

c) The 7 temperature sensors are as described in Subsection F.4;

d) The connection between the temperature sensor and sterilisation chamber has no affect on the vacuum tightness and pressure tightness of the sterilizer;

e) The medium pipeline connection should meet the requirements of Subsection 5.5.1.

6.8.3.3.2 Test procedures

a) The connector passing through the temperature sensor links the temperature sensor to the sterilisation chamber;

b) Perform the vacuum leakage test as specified in Subsection 6.8.3.4. If the flow speed of leaked gas exceeds that specified in Subsection 5.8.3.4, the test should be stopped;

c) Place a temperature sensor on the reference measurement point;

d) Select the sterilisation cycle to be tested;

e) Run the sterilisation cycle under no-load conditions;

f) Open the package of the test pack. Put 5 temperature sensors inside the standard test pack at the positions indicated in Figure 5. Put another one beneath the top cotton cloth inside the pack. As mentioned in Subsection F.1, the test pack should be re-packed.

g) As mentioned in Subsection F.7, the standard test pack and other simulated loads are put into the sterilisation chamber;

h) Run a sterilisation cycle, and perform the following measurements:

— Check and record the required time, number of pulses, temperature, pressure and vacuum degree of the various important stages of the entire sterilisation process, e.g. the transition between sterilisation stages;

— Check and record the temperature and pressure of sterilisation chamber during the beginning, middle and end of the sterilisation holding stage;

— Make sure that the recording device installed in the sterilizer has recorded the entire sterilisation cycle (please refer to Subsection 5.6.3).

i) Upon completion of the test, the following operations should be run continuously:

— Check whether there is any visible indication showing that the entire test cycle has been completed;

— Check the test record, and include the material of standard test pack. It should meet the performance requirements specified in Subsection 5.8.3.3;

— Check the test record. It should meet the requirements of sterilisation cycle.

6.8.3.4 Vacuum leakage test

6.8.3.4.1 Outline

The test is to prove that in a vacuum state, the gas volume leaked into the sterilisation chamber is not great enough to obstruct the steam penetration load, and would not lead to re-pollution of the load during the drying period.

6.8.3.4.2 Test equipment

a) Pressure test meter that meets the regulations of Subsection F.3.

If the sterilizer is equipped with an absolute pressure meter that meets the regulations of Subsection F.3, it is not required to increase other meters.

b) The error margin of the timing meter within 15 minutes should not exceed ± 0.5 second.

6.8.3.4.3 Test procedures

a) Connect the pressure test meter to the sterilisation chamber. Let the designed operating pressure reach 380kPa.

b) Stabilise the temperature of sterilisation chamber as follows:

— If the pressure vessel has a heating jacket attached, a sterilisation cycle should be run under no-load conditions;

— If the pressure vessel does not have a heating jacket attached, it should be ensured that the temperature of the sterilisation chamber is not over 20°C higher than the ambient temperature.

Note: For example, in an enclosed pressure vessel at 4kPa, within the range of 20°C ~ 140°C, whenever the temperature changes by 10°C, the pressure change is about 0.1kPa. When it is at 7kPa, the change is about 0.2kPa. If the temperature change exceeds 10°C during the test period, the test result may be affected.

c) Under stable temperatures (with the exception of fixed devices and the necessary surveillance sensor), the test cycle is commenced, with the sterilisation chamber being under no-load conditions. When the pressure of the sterilisation chamber is 7kPa or below, all the valves connected to the sterilisation chamber should be closed, and the vacuum valve should be stopped. Check and record the time (t_1) and pressure (p_1). Wait for at least 300 seconds, but not over 600 seconds, to let the condensed water inside the sterilisation chamber gasify. After that, check and record the pressure (p_2) and time (t_2) inside the sterilisation chamber. Then, (600 ± 10) seconds later, once again check and record the pressure (p_2) and time (t_2).

Note: Sterilizers can be designed with automatic vacuum leakage test cycles. The displayed unit of leakage rate is kPa/min.

d) Upon completion of the test, calculate the rate of pressure rise within 600 seconds. The result should meet the regulations of Subsection 5.8.3.4.

Note: If the numerical value of ($p_2 - p_1$) is greater than 2kPa, it may be because excessive amounts of condensed water start to appear in the sterilisation chamber.

6.8.4 Dryness test

6.8.4.1 Dryness of fabric test in small loads

Note: The small-load fabric dryness test is to ensure that, after the standard sterilisation cycle without any extension of drying time, the drying effect of load is not affected.

a) Test equipments

— The standard test pack that meets the requirements of F.1 is for sterilizers loading more than one sterilisation module. The small-sized test pack that meets the regulations of F.2 is for sterilizers loading one

sterilisation module only;

— Balance, with its measurement range being 8kg minimum, and its accuracy being 1g minimum;

— Stopwatch;

— The medium pipeline connection should meet the requirements of Subsection 5.5.1.

b) Test procedures

— Make sure that the material in the test pack meets the requirements mentioned in Subsection F.1 or F.2;

— Weigh the test pack (m_1);

— Select the sterilisation cycle to be tested;

— Run the test cycle under no-load conditions;

— Place the test pack at the centre of the sterilisation chamber, at a height of between 100mm ~ 200mm. For sterilizers that can handle a sterilisation module only, the test pack should be placed on the bottom of the sterilisation chamber;

Put the test pack in sterilisation chamber, and start the sterilisation cycle within 60 seconds;

— Within 120 seconds after the completion of sterilisation, weigh the mass of the test pack (m_2), and record the result;

— Calculate (in percentage) the change of water content inside the test pack by equation (1):

$$\Delta m = \frac{(m_2 - m_1)}{m_1} \times 100\% \cdots\cdots (1)$$

where:

Δ m denotes the percentage for the change of water content;

m_1 denotes the mass of the test pack before sterilisation, in unit g.

m_2 denotes the mass of the test pack after sterilisation, in unit g.

— Check the above results, which should meet the requirements of Subsection 5.8.4.1.

6.8.4.2 Full load fabric dryness test

Note: A full-load fabric dryness test is to determine whether or not, during the sterilisation cycle, under the full load condition of fabrics, the standard test pack would absorb excessive moisture.

a) Test equipments

— Full-load fabrics, as described in F.7;

— Balance, with its measurement range being 8kg minimum, and its accuracy being 1g minimum;

— Stopwatch;

— The medium pipeline connection should meet the requirements of Subsection 5.5.1.

b) Test procedures

— Make sure that the material of test pack meets the requirements described in Subsection F.1;

— Weigh the test pack (m_1);

— Select the sterilisation cycle to be tested;

— Run the test cycle under no-load conditions;

— Put the test pack in sterilisation chamber according to the description of Subsection F.7.

Put the test pack into sterilisation chamber, and start the sterilisation cycle within 60 seconds;

— Within 120 seconds after the completion of sterilisation, weigh the mass of the test pack (m_2), and record the result;

— Calculate (calculate in percentage) the change of water content inside the test pack by equation (1);

— Check the above result, which should meet the requirements of Subsection 5.8.4.2.

6.8.4.3 Dryness test in times of metal load

In the metal-load dryness test, metal and a reference load are used together. The test is to prove that the issue of wet packs would not be caused during routine production. If a wet pack is found after the test, it may be caused by the kind of load and its position in the sterilisation chamber.

a) Test equipment

— Test pack, with the metallic material as mentioned in F.9;

— Balance, with its measurement range being 8kg minimum, and its accuracy being 1g minimum;

— Stopwatch;

— The medium pipeline connection should meet the requirements of Subsection 5.5.1.

b) Test procedures

— Make sure that the condition of the test load is the same as the surrounding environment;

— Weigh the weight of test pack and metal, and record its mass (m_1);

— Select the sterilisation cycle to be tested;

— Run the test cycle under no-load conditions;

— Position the test pack and metal load on a lower shelf.

— Use sterilisation baskets, with each of them loaded with around 15kg of steel-made items. Load the sterilisation chamber to a full-load situation. The conditions of all the items should be the same as the surrounding environment;

— Check whether the temperature inside the test pack is within the range of (25 ± 2)^{o}C, and start the sterilisation cycle within 60 seconds;

— Upon the completion of sterilisation cycle, take out the test pack and metal from the sterilisation chamber, and complete weighing within 5 minutes. Record its mass (m_2);

— Calculate (calculate in percentage) the change of water content by equation (2):

$$\Delta m = \frac{(m_2 - m_1)}{m_1} \times 100\% \cdots\cdots (2)$$

where:

Δ m denotes the percentage for the change of water content;

m_1 denotes the mass of the test pack and metal before sterilisation, in unit g.

m_2 denotes the mass of the test pack and metal after sterilisation, in unit g.

— Check the above results, which should meet the requirements of Subsection 5.8.4.3.

6.9 Noise test

When a sterilizer is running normally, a sound level meter is placed at 1 meter from the sterilizer, and at a height of 1 meter above the floor. Measure the noise from four directions: left, right, front and back. The results should meet the requirements of Subsection 5.9.

6.10 Test of pressure change rate

The test of pressure change rate is to prove that in the sterilisation cycle, the pressure change rate inside the sterilisation chamber does not exceed the limited value that would cause damage to the package. Fixing this limited value is to ensure meeting the performance requirements of packaging material indicated in GB/T 19633. This is a synthetic consideration for the selection of both the economical packaging material as well as the short and effective sterilisation cycle.

6.10.1 Equipment

Pressure recording equipment, as shown in Subsection F.6.

6.10.2 Procedures

6.10.2.1 Connect the pressure recording equipment securely (please refer to Subsection 5.4.3.1).

6.10.2.2 Perform a vacuum leakage test according to the test methods of Subsection 6.8.3.4. If the vacuum leakage rate exceeds that specified in Subsection

5.8.3.4, the test should be stopped.

6.10.2.3 Select the sterilisation cycle to be tested.

6.10.2.4 Run the sterilisation cycle under no-load conditions, and check and record the time, temperature and pressure at all the important stages of sterilisation cycle.

6.10.2.5 Upon completion of the test, continue the following procedures:

— Check the specified records above, which should meet the requirements of sterilisation cycle;

—Check and continuously measure the pressure difference of each interval of 3 seconds. It should meet the requirements of Subsection 5.10.

6.11 Test of safety requirements

6.11.1 The electrical safety test is performed according to the methods specified in GB 4793.1 and GB4793.4. It should meet the requirements of Subsection 5.11.1.

6.11.2 The electromagnetic compatibility test is performed according to the methods specified in GB/T 18268-2000. It should meet the requirements of Subsection 5.11.2.

6.12 Labelling test

Perform a visual inspection. It should meet the requirements of Subsection 5.12.

Appendix A
(Informative Appendix)
Environmental factors

A.1 Environmental factors affecting the life of the steam sterilizer

A.1.1 Adapt the steam for sterilisation

The water source used for steam sterilisation should be normal drinking water that has been softened, demineralised and deionised.

A.1.2 Environmental effects

The process of gasifying water into steam in different states, and condensing steam back into water is a circulated technological process. This is an important part of the science of ecology. Therefore, the steam sterilisation process itself would not have any definite effects on the environment.

Steam is a gas that is non-toxic, non-irritating, and would not cause an allergic reaction. With the exception of accidental circumstances that may cause burns to the body, steam would not be a hazard to the local environment or people.

The environmental effects caused by steam sterilisation by using a sterilizer are mainly the several mutually independent aspects as follows;

— When saturated steam is caused in the process of test and normal running, water resources and energy have to be used;

— In the process of test and normal running, any actions aside from the purposes of equipment running and cooling, mean that water resources have to be consumed;

— Effects caused to local environment in the process of normal running;

— Discharge of polluted waste water in the process of normal running;

— Use, cleaning and disposal of the used items in the process of test and normal running;

— Discarding of equipment.

Appendix B
(Informative Appendix)
Identification standard of sterilizers of the same module

B.1 The sterilizers defined as being of the same module should:

— Be equipped with the same number of doors at the same positions. In this respect, when it is proved in tests that the given size of door, type of door, (single or double) of a sterilisation chamber would have no effect on the load, they are regarded as sterilizers of the same module;

— All the medium supply systems should be connected to the sterilisation chamber from the same direction. If the method of symmetrical connection is adopted, they are sterilizers of the same module;

— In the same control system, all the sensors should be installed at the same position and in the same direction. Any changes and limited value changes from the control system and not affecting the technological procedures should be sterilizers of the same module;

— Adopt the same sterilisation cycle.

When the design of the air removal stage of the sterilisation cycle is changed, the sterilisation effect of a resin load has to be assessed. Using the test methods specified in Subsection 6.8.2, this point can be realised.

B.2 The design of other aspects remains unchanged. The following changes do not necessitate a new unit:

— The height for installing the sterilisation chamber of sterilizer is changed;

— The dimensional difference for the sterilisation chamber does not exceed ± 10%;

— Although the plateau period in the sterilisation cycle is extended, the sterilisation temperature is the same, and the air removal stage is consistent;

— Any change in design or any change by the parts supplier, as long as documents are provided to prove that the performance of the sterilizer is not affected.

Appendix C
(Informative Appendix)
Mass of steam and water

Table C.1 Quality index of supplied water

Item	Index
Steam residue	≤ 10mg/L
Oxidized silicon, SiO_2	≤ 1mg/L
Iron	≤ 0.2mg/L
Chromium	≤ 0.005mg/L
Lead	≤ 0.05mg/L
Heavy metals other than iron, chromium, or lead	≤ 0.1mg/L
Chlorine ion (Cl^-)	≤ 2mg/L
Phosphate (P_2O_5)	≤ 0.5mg/L
Electrical conductivity (at 25°C)	≤ 5μs/cm
pH value (acidity)	5 ~ 7.5
Appearance	Colourless, clean, no sediment
Hardness (total number of alkaline metal ions)	≤ 0.02mmol/L
Note: The result of the consistency inspection should meet the regulations of the known analytic method.	

Table C.2 Quality index of steam condensate

Item	Index
Oxidized silicon, SiO_2	≤ 0.1mg/L
Iron	≤ 0.1mg/L
Chromium	≤ 0.005mg/L
Lead	≤ 0.05mg/L
Heavy metals other than iron, chromium, lead	≤ 0.1mg/L
Chlorine ion (Cl^-)	≤ 0.1mg/L
Phosphate (P_2O_5)	≤ 0.1mg/L
Electrical conductivity (at 25°C)	≤ 3μs/cm
pH value (acidity)	5~7
Appearance	Colourless, clean, no sediment
Hardness (total number of alkaline metal ions)	≤ 0.02mmol/L
Note: Please refer to the test method of steam quality in Chapter 22 of EN-285: 2006.	

Appendix D
(Informative Appendix)
Materials

D.1 General rules

D.1.1 This Appendix is a selection of guidelines for manufacturing the materials used in a steam sterilizer. It should meet the "Supervision Regulations on Safety Technology for Pressure Vessels" and the related national regulations. In this respect, the information provided by this Appendix cannot replace the decisions of the manufacturers, and the use of other materials of the same quality may not be ruled out.

D.1.2 When selecting material, the following factors should be considered:

— The article to be sterilised in the sterilisation chamber may be affected by corrosion;

— There are substances that can easily cause corrosion in sterilisation steam or cooling medium (e.g. free oxygen or carbon dioxide);

— The possibility of an anti-corrosion layer forming on the surface;

— Effects caused to the environment.

D.1.3 Tables D.1, D.2 and D.3 explain the combinations of materials in serial numbers from I to VII.

I Stainless steel

II Carbon steel

III Carbon steel, carbon steel for gold plating

IV Copper

V Aluminium, aluminium alloy

VI Copper alloy

VII Others

Table D.1 Combinations of materials

Pressure vessel for sterilizer and steam generator	Suggested combination of materials			
	Group A	Group B	Group C	Group D
Sterilisation chamber	I	III	IV	V
Jacket	I	II	IV	V
Door	I/ III	I/III	IV/VI	V
Interior devices in the sterilisation chamber	I	I	VI	V
Outer frame of pressure vessel	I/II	II	IV	V
Coating	I[1)]	I[1)]	I[1)]	I/V
Frame	I/II	II	II	II/V

Steam generator built-in sterilisation chamber	I/III	III	IV	V
Steam generator inside the sterilizer stand or independent steam generator	I/III	I/III	IV	I/III
Note: [1)] Where the coating is stainless steel				

D.2 Pipeline and connection

D.2.1 Mediums having contact with sterilizer load:

a) Steam for sterilisation;

b) Deionised water;

c) Germ-free air;

d) Condensate

Table D.2 Combinations of materials

Applicable to pipelines with circulating mediums in contact with load	Suggested combination of materials		
	Group E	Group F	Group G
Pipe	I	I	IV
Connection	I	I	VI
Lapped flange	II	II	II
Flange for welding use	I	I	--
Holding collar (welded)	I	I	IV
Valve sleeve	I	VI	VI
Conic valve and washer	I	I	VI
Sensor	I	I	IV
Pipeline of pressure meter	I	IV	IV
Pressure meter	I	VI	IV/VI
Note: In order to prevent noise and vibration, part of the sterilizer pipelines should use connectors made of highly elastic material or soft metal. For this kind of connector and other connected pipelines, there should be the same consideration of suitability.			

Table D.3 Combinations of materials

Applicable to pipeline with circulating mediums not in contact with load	Suggested combination of materials		
	Group H	Group J	Group K
Pipe	IV	IV/II	IV/II
Connection	IV/VI	II/VI	II/VI
Lapped flange	II	II	II
Flange for welding use	--	II	II
Holding collar (welded)	IV	IV	IV
Valve sleeve	VI	VI	VI
Conic valve and washer	I/VI	VI	VI

Sensor	I	I	IV
Pipeline of pressure meter	I	IV	IV
Pressure meter	I	IV/VI	IV/VI
Pipeline of compressed air for control use	VII	VII	VII
Note: In order to prevent noise and vibration, part of the sterilizer pipelines should use connectors made of highly elastic material or soft metal. For this kind of connector and other connected pipelines, there should be the same consideration of suitability.			

D.2.2 Mediums having no contact with sterilised items:

a) Industrial-use steam;

b) Cooling water;

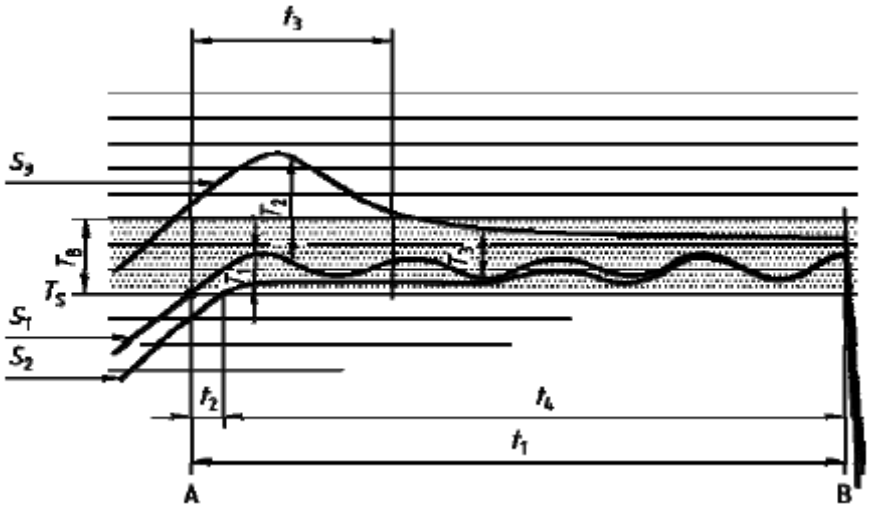
c) Discharged water;

d) Compressed air for control use;

e) Steam and/or air in a vacuum state.

Appendix E
(Normative Appendix)
Acceptable ranges of temperature and plateau period during small-load temperature test period

The acceptable ranges of temperature and plateau period in small-load temperature tests are shown in Figure E.1.



Main points

A	Plateau period started	S_1	Refer to temperature curve of measurement point
B	Plateau period completed	S_2	Temperature curve at central point of test pack
T_S	Sterilisation temperature	S_3	Temperature curve 50mm above test pack
T_B	Sterilisation temperature band	T_1	Maximum temperature difference between reference temperature point and temperatures of different points of test pack within holding time
t_1	Plateau period		
t_2	Equilibration time		
t_3	60 seconds	T_2	Maximum temperature difference between reference temperature point and temperature of measurement point above test pack within 60 seconds before plateau period
t_4	Holding time		
		T_3	Maximum temperature difference between reference temperature point and temperature of measurement point above test pack after t_3 (60 seconds).

Figure E.1 Acceptable ranges of temperature and plateau period during small-load temperature test period

Appendix F
(Normative Appendix)
Test instruments, equipments and materials

F.1 Standard test packs

Note 1: The test pack determines whether steam can rapidly penetrate the test pack evenly when the parameter cycle has reached the preset value.

Note 2: Used in BD tests, small load tests, fabric tests, dryness tests, and can form a full load together with other materials.

F.1.1 Standard test packs can be used repeatedly. When the requirements of Subsections F.1.3 and F.1.4 have been met, standard test packs can also be used for continuous tests. The environmental factors affecting cleaning intervals, as well as the cleaning method, should also be considered.

F.1.2 Standard test packs should be assembled using bleached pure cotton cloth sheets with dimensions of around 900mm × 1200mm. The longitudinal thread count should be (30±6) lines/cm^2, the latitudinal thread count should be (27±5) lines/cm^2, and the weight should be (185±5)g /cm^2, without folded edges.

F.1.3 Whether the cotton cloth sheet is new or used, it should be washed, without using any fabric detergent.

Note: Fabric detergent would affect the nature of fabrics, and may contain volatile compounds that would lead to the production of non-condensed gas.

F.1.4 Standard test packs can only be used after it has undergone dryness stabilisation in an environment at a temperature of 20^{o}C ~ 30^{o}C and a relative humidity of 40% ~ 60%.

F.1.5 Standard test packs should be folded and assembled according to the regulations of Figure F.1.

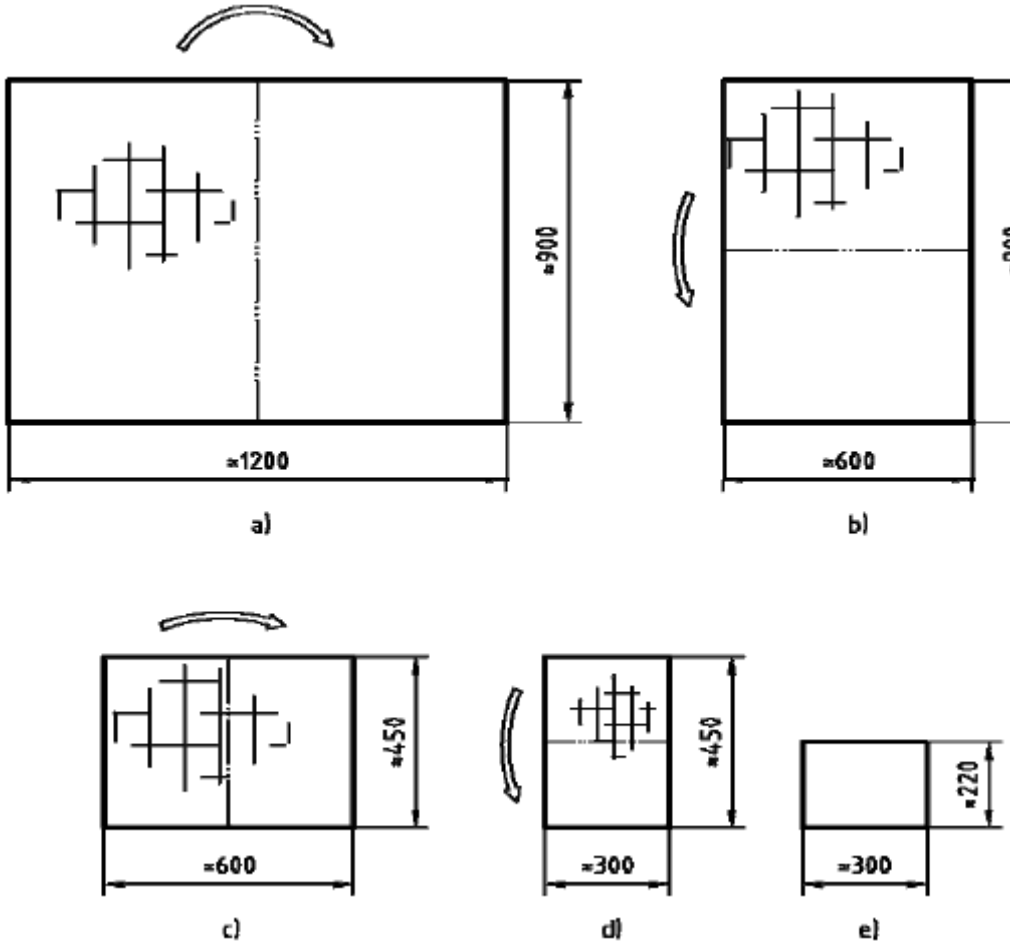


Figure F.1 Folding and assembling of standard test pack

Main points

a) 1 layer, no folding	b) 2 layers, folded once	e) 4 layers, folded twice
d) 8 layers, folded three times	e) 16 layers, folded four times	—

F.1.6 Cloth sheets should be folded to around 220mm × 300mm. After they are pressed flat by hand, they are stacked up to a height of around 250mm. Standard test packs should use similar wrapping cloths for wrapping up. Use a tying string with a width of no more than 25mm for tying firmly. The total weight of a standard test pack should be 7kg ± 0.14kg (around 30 cloth sheets are required). After a test cycle has ended, the standard test pack should be taken out from the sterilizer and ventilated at a temperature of 20°C ~ 30°C and a relative humidity of 40% ~ 60%. Only after this process can it be used continuously. In each timed interval of use, the standard test pack should be stored in an environment at a temperature of 20°C ~ 30°C and a relative humidity of 40% ~ 60%.

Note: After use, the standard test pack has to be compressed. If a standard test pack at a thickness of 250mm has a weight exceeding 7.14kg, the standard test pack cannot be used anymore.

F.1.7 Before using a standard test pack, a calibrated meter should be used to

measure its temperature and humidity. Make sure that the conditions inside the pack are at a temperature of 20°C ~ 30°C and a relative humidity of 40% ~ 60%; otherwise it cannot be used in testing.

F.1.8 A test pack can be made of different materials, different sizes and weights, provided that it has the same effect as a standard test pack.

F.2 Small-sized test pack

F.2.1 The test pack is exclusively for sterilizers that can load one sterilisation module only, to test whether steam can rapidly penetrate the test pack evenly under the specified conditions when the cycle parameter has reached the preset value.

It can be used to perform BD tests, small load tests and dryness tests. It can also form a full load together with other materials.

Test packs can be used repeatedly. When the requirements of Subsections F.2.3 and F.2.4 have been met, standard test packs can also be used for continuous tests. The environmental factors affecting cleaning intervals, as well as the cleaning method, should also be considered.

F.2.2 Standard test packs should be assembled using bleached pure cotton cloth sheets with dimensions of around 900mm × 1200mm. The longitudinal thread count should be (30±6) lines/cm^2, the latitudinal thread count should be (27±5) lines/cm^2, and the weight should be (185±5)g /cm^2, without folded edges.

F.2.3 Whether the cotton cloth sheet is new or used, it should be washed, without using any fabric detergent.

Note: Fabric detergent would affect the nature of fabrics, and may contain volatile compounds that would lead to production of non-condensed gas.

F.2.4 Standard test packs can only be used after it has undergone dryness stabilisation in an environment at a temperature of 20°C ~ 30°C and a relative humidity of 40% ~ 60%.

F.2.5 Standard test packs should be folded and assembled according to the regulations of Figure F.1.

F.2.6 Cloth sheets should be folded to around 220mm × 300mm. After they are pressed flat by hand, they are stacked up to a height of around 250mm. Standard test packs should use similar wrapping cloths for wrapping up. Use a tying string with a width of no more than 25mm for tying firmly. The total weight of a standard test pack should be 7kg ± 0.14kg (around 30 cloth sheets are required). After a test cycle has ended, the standard test pack should be taken out from the sterilizer and ventilated in an environment at a temperature of 20°C ~ 30°C and relative humidity of 40% ~ 60%. Only after this process can it be used continuously. In each timed interval of use, the standard test pack should be stored in an environment at a temperature of 20°C ~ 30°C

and a relative humidity of 40% ~ 60%.

Note: After use, the standard test pack has to be compressed. If a standard test pack at a thickness of 250mm has a weight exceeding 7.14kg, the standard test pack cannot be used anymore.

F.2.7 Before using a standard test pack, a calibrated meter should be used to measure its temperature and humidity. Make sure that the conditions inside the pack are at a temperature of 20°C ~ 30°C and a relative humidity of 40% ~ 60%; otherwise it cannot be used in testing.

F.3 Pressure meter

F.3.1 The pressure meter should be used to check the pressure display and recording equipment.

Note: Other suitable meters can be used, provided that they contain sensors and have an accuracy range that meets the requirements.

F.3.2 Within the pressure range of 0 ~ 400kPa, the resolution should be 1kPa minimum. For the vacuum leak test instrument, within the measurement range being used, the resolution should be 0.1kPa minimum [please refer to Subsection F.3.3.b].

F.3.3 The pressure meter should:

a) Have a measurement range of at least 0 ~ 400kPa, and an accuracy of measurement range of level 0.25 minimum;

b) If used in a vacuum leakage test, it should possess a measurement range specified by the sterilizer manufacturer. Furthermore, within the pressure range in the testing process, the accuracy of pressure difference at 1.5kPa should not be lower than 0.1kPa.

   Under the temperature conditions that the pressure sensor is used, the temperature coefficient of the measurement system should not exceed 0.01%/°C.

F.3.4 Each set of pressure systems should be calibrated according to the corresponding national or industrial standard.

F.3.5 Each set of pressure systems should be calibrated according to the manufacturer's regulations.

F.4 Temperature sensor

F.4.1 The temperature sensor should be used to sense the temperature at the specific positions in the tests mentioned in this Standard.

F.4.2 The temperature sensor should be platinum resistant, and meet the thermoelectric coupling requirements of Grade A in JB/T 8522-1997 and Grade 1 tolerance table in GB/T 16839.2-1997.

F.4.3 The cross-section area of the sterilizer's useable space and any of its wire connection parts should not exceed 3.1mm^2.

F.4.4 The running features of the temperature sensor should not be affected by the environment in which it is situated (e.g. pressure, steam or vacuum).

F.5 Temperature recording equipment (if applicable)

F.5.1 Temperature recording equipment should be used together with the sensor. It measures the temperature at the specific points in the recording tests mentioned in this Standard. It can also be used to check other temperature gauges on the sterilizer.

F.5.2 The recording equipment should be able to record the temperatures tested by at least 7 temperature sensors. The sampling channels can be multiple or individually independent. The sampling rate of each sampling channel should not be over 1 second. All the data are used to explain the test result.

F.5.3 The graduation range of the simulated meter should be between 0^{o}C ~ 150^{o}C. The minimum graduation interval should not exceed 1^{o}C. The recorded paper speed should not be lower than 15mm/min. The resolution should be 0.5^{o}C or better.

F.5.4 The increments of the numerical meter and record should not exceed 0.1^{o}C, and the graduation range should be between 0^{o}C ~ 150^{o}C.

F.5.5 For the test performed at the ambient temperature of (20 ± 3)^{o}C, the error margin between 0^{o}C and 150^{o}C (exclusive of temperature sensor) should not exceed ± 0.25%.

F.5.6 The additional error caused by the change in ambient temperature should not exceed 0.04 ^{o}C/^{o}C.

F.5.7 Calibration should be made according to the national standard or industrial standard.

F.5.8 Instruments should be calibrated according to the manufacturer's indications. When calibrating, any single temperature should be selected within the sterilisation temperature band. After calibration, the difference between the temperature tested when all the temperature sensors have been immersed in the temperature source at a known temperature and the temperature measured in the sterilisation temperature band should not exceed 0.5^{o}C.

F.5.9 When the site has been adequately installed, the temperature system should conduct verification tests in an independent temperature source within the sterilisation temperature band through a temperature.

F.5.10 Temperature sources should possess the following characteristics:

— A standard thermometer that includes the range of 110^{o}C ~ 140^{o}C, and where the minimum graduation interval should not exceed 0.2^{o}C.

— It should have a test slot with dimensions sufficient to place at least 7

temperature sensors as described in F.4. The temperature change inside the slot should not exceed 0.2°C. Within the range of 110°C ~ 140°C, the control accuracy should be within ± 0.1°C.

F.6 Pressure recording equipment

F.6.1 Pressure recording equipment should be used together with sensing components to test the absolute pressure of the sterilizer during a sterilisation cycle. It can also be used to check the pressure meter on the sterilizer.

F.6.2 It is possible for the equipment to work with temperature recording equipment to serve as additional signals for calibrated pressure. The sampling rate of each sampling channel should not be over 1 second. All the sampling data should be used to explain the test result.

F.6.3 The graduation range of the simulated equipment should include the absolute pressure of 0kPa ~ 400kPa. The minimum graduation interval should not exceed 4kPa. The recorded paper speed should not be lower than 15mm/min. The resolution should be 2kPa or better.

F.6.4 The increments of the numerical equipment and its record should not exceed 1kPa, and the graduation range should include the absolute pressure of 0kPa ~ 400kPa.

F.6.5 Measurements should be made within the absolute pressure range of 0kPa ~ 400kPa and at the environmental temperature of (20 ± 3)°C. The error margin of the measurement system should not exceed ± 0.5%.

F.6.6 If a pressure sensor is used, the temperature coefficient of the measurement system should not exceed 0.01%/°C.

F.6.7 The additional error caused by the change in ambient temperature should not be greater than 0.02%/°C.

F.6.8 The natural frequency of the sensor and connecting pipe should not be less than 10Hz. The time constant of a pressure rise (relative humidity at 0% ~ 63%) should not be above 0.04 second.

F.6.9 Calibration should be made according to the applicable national standard.

F.6.10 When the equipment is connected to a pressure-sensitive component, calibration should be made according to the manufacturer's instructions. Meanwhile, the calibration range should include the pressure within the sterilisation pressure section.

F.7 Full load, fabrics

F.7.1 The test-pack-simulated sterilizer can handle the maximum fabric mass, and test whether steam can rapidly penetrate the fabric evenly and achieve sterility once

the cycle parameters have reached the preset values.

Full-load fabrics can be used repeatedly. When the requirements of Subsections F.7.3 and F.7.4 have been met, standard test packs can also be used for continuous tests. The environmental factors affecting cleaning intervals, as well as the cleaning method, should also be considered.

F.7.2 A full load should be composed of folded cloth sheets and a standard test pack, as described in F.1.

F.7.3 Each cloth sheet should contain at least 50% mass ratio of cotton fibre, and should be at a density of around 200g/cm^2. All new or dirty cotton cloth sheets should be washed, with no fabric detergent added (please refer to F.1).

F.7.4 After being baked dry, cloth sheets should be ventilated in an environment at a temperature of 20^{o}C ~ 30^{o}C and a relative humidity of 40% ~ 60% for at least 1 hour.

F.7.5 After ventilation and drying, the cloth sheets are folded as packs. The mass of each pack is 7.5kg ± 0.5kg.

F.7.6 Standard test packs should be placed in the location in the sterilizer where the manufacturer thinks it most difficult to perform sterilisation. The remaining useable space can be filled with other packs of cloth sheets. They are placed in the sterilisation baskets with dimensions similar to the standard sterilisation module. Fill the rest of the useable space of the sterilisation chamber. Make sure that the load can easily be added and removed from the chamber.

F.7.7 The fabric weight of each sterilisation basket should be around (7.5 ± 0.5)kg.

F.8 Test pack, resin

F.8.1 The test pack is used to represent the resin load, e.g. the long pipeline where it is difficult to perform sterilisation.

The resin test pack is made of the material available for repeated use in continuous tests. When handling the outer package, the manufacturer's requirements should be followed.

F.8.2 Each test pack is composed of several resin items. The total height should be 100mm, and the volume size is equivalent to half of a sterilisation module. In these small packs, 3 packs contain the following test samples. The rest of the small packs should be loaded with a natural resin pipe at a length of 1500mm, outer diameter of 5mm and inner diameter of 3mm. The resin pipe should be coiled on the same level. All the small packs should use the paper-plastic packaging bag at a standard width of 90mm according to the standard, GB/T 19633. When arranging each bag, the paper sides should be facing each other.

F.8.3 Each test sample should contain 3 biological loads meeting the standard GB18281.3 (the load is a glass tube at an outer diameter of 4mm, inner diameter of 2.5mm and length of 45mm). The glass tube is inserted in a natural resin pipe at a length of 1500mm, outer diameter of 5mm and inner diameter of 3mm. A glass tube load should be placed in the central part of the resin pipe. The other two loads are respectively placed at 200mm from the two ends of the resin pipe.

F.8.4 Small packs should be arranged with the paper sides facing each other. The 3 small pack containing test samples should be placed in the test pack at the heights of 25mm, 50mm and 75mm respectively.

Note: A loading vessel should be used, e.g. a stainless steel basket for loading test packs.

F.8.5 Store test packs at a temperature of 20°C ~ 30°C and a relative humidity of 40% ~ 60% for at least 1 hour.

F.8.6 Before use, the test pack should be stored in an environment satisfying the above conditions.

F.9 Test pack, metal

F.9.1 The test pack represents metal items, e.g. instruments that are difficult to dry.

A metallic test pack can be used repeatedly, and also be used in continuous tests.

F.9.2 The sterilizer load should contain test boxes with stainless steel baskets and a certain quantity of metallic screws wrapped by textile material.

F.9.3 The test box should:

— Be sealed with a plate, and meet the regulations of Figure F.2.

— Not contain any holes other than those shown in Figure F.2

— Be made of stainless steel, at a thickness of 1mm.

F.9.4 The basket should:

— Be made of stainless steel;

— Have dimensions of the bottom lattice at 5mm × 5mm;

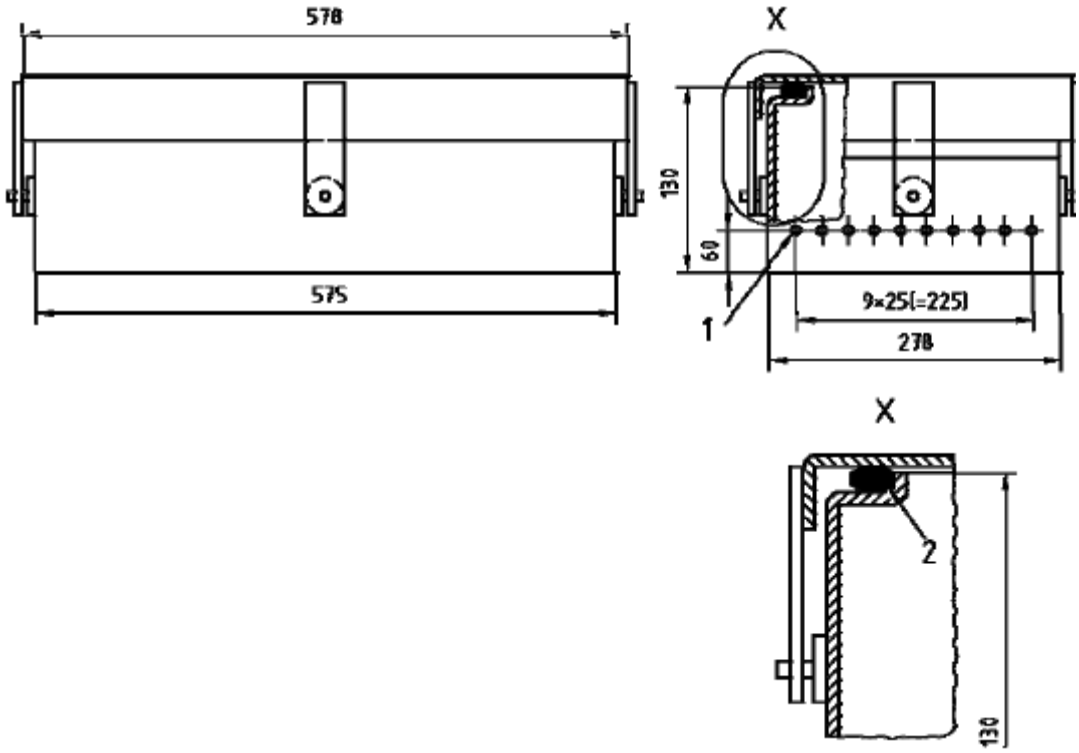
— Have dimensions of the lateral lattice at 5mm × 5mm;

— Have a distance between the contact surface of the load and the bearing and supporting surface of basket at around 6mm;

— Be able to support an evenly distributed load of 10kg;

— Have maximum dimensions of (480 ± 5)mm length, width of (250~254)mm and height of (50~55)mm;

— Have a mass of (1.3 + 0.1)kg.



The dimensions are in mm.

Main points:

1. Drill 10 holes of Φ 4mm on each of the two lateral sides.
2. Use a silicon sealing ring Φ6, length 1550, to drill up to the top cap inside. After the top cap is closed, it is pressed tightly, and its diameter is shrunk to be 90%.

Figure F.2 Detailed diagram of metallic test box

F.9.5 The metallic screws used for the test load should be:

— Stainless steel.

— Hexagonal;

— Of a total mass of (8.6 ± 0.1)kg;

— Clean, dry, with no oil or dirt.

F.9.6 The fabric material used for the test should:

— The test pack should be composed of non-fat pure cotton cloth sheets. The dimensions are around 900mm × 1200mm. The longitudinal thread count should be (30±6) lines/cm^2, and the latitudinal thread count should be (27±5) lines/cm^2;

— Whether the cotton cloth sheet is new or used, it should be washed, without using any fabric detergent.

— Undergo drying and ventilation treatment;

— Be stored in an environment at a relative humidity of 40% ~ 60% and a temperature of 20^{o}C ~ 30^{o}C for at least 1 hour.

Note: Prior to packaging, the article to be packaged must have the same ambient temperature as the surrounding area.

F.9.7 All the metal items inside the test pack should reach temperature equilibration under a temperature of (23 ± 2)°C.

F.9.8 The test pack should be assembled as follows:

— Place the stainless steel basket on the cloth sheet;

— Place the screws evenly on the stainless steel basket;

— Use the cloth sheet to wrap the stainless steel basket loaded with screws;

— Put the wrapped stainless steel basket in the test box.

F.9.9 Before use, the test pack should be stored in an environment satisfying the above conditions.

F.10 Hollow load test process challenge device (PCD)

F.10.1 The hollow load test process challenge device (PCD) is composed of pipe cap, connector, indicator fixer and hose, as shown in Figure F.3. Chemical indicators should meet the requirements of GB18282.1. The manufacturer should provide the selection and application method of chemical indicators.

F.10.2 PCD should meet the following requirements:

— Material: polytetrafluoroethylene (PTFE);

— Thickness of pipe wall: (0.5 ± 0.025)mm;

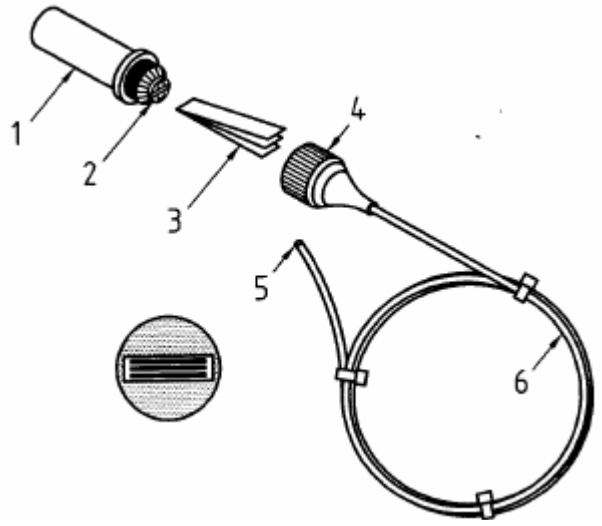
— Inner diameter of pipe: Φ (2.0 ± 0.1)mm;

— Length of hose: (1500 ± 15)mm;

— Weight of indicator fixer: (10.0 ± 0.1)g;

— Free capacity inside the PCD: Total capacity inside the device minus (6 ± 1)% of the capacity of indicator fixer.

Note: Similar type materials can be used. When using other materials, the wall thickness and the weight of the indicator fixer can be changed accordingly.



1 — Pipe

2 — Indicator fixer

3 — Indicator

4 — Connector

5 — Opening end

6 — Hose

Figure F.3 Example of hollow load test process challenge device (PCD)

Appendix G
(Informative Appendix)
Information and documents that manufacturers should provide

G.1 Documents that manufacturers should provide

G.1.1 Test and inspection records, which are sufficient to prove that the sterilizer purchased by the purchaser meets the requirements (please refer to Subsection G.2.4).

G.1.2 These documents should include:

a) Certifying documents for calibrated instruments;

b) Documents certifying that both the function of safety devices and their settings meet the requirements;

c) Detailed setting parameters of the automatic controller, including the pressure, temperature and time of sterilisation cycle (e.g. changing situation of each stage or sub-stage);

d) Setting the function of the air detection device (if applicable);

e) Declaration meeting the requirements of this Standard;

f) Other declarations of the operating cycle and usage expansion not specified in this Standard.

G.2 Information that manufacturers should provide

G.2.1 The contents specified in this clause can assist the purchaser in preparation for the installation, installation, operation and routine maintenance of the sterilizer.

G.2.2 The overall information specified in Subsections G.2.4 and G.2.5 can be provided before delivery of the sterilizer, or part of the information (divided into two parts) can be provided before delivery and before the commencement of installation work respectively.

G.2.3 Before delivery and installation of the sterilizer, the following information should be provided to the purchaser:

a) Installation instructions, which should include the maximum load-bearing requirement of the floor after the sterilizer pressure vessel is fully loaded with water, the overall dimensions of the sterilizer, its overall mass, the

required moving space and the size of major large parts;

b) Type of power source, e.g. whether it is direct current or alternating current, single-phase or three-phase, its voltage and frequency (including the maximum value and minimum value, as well as the maximum continuous power, in the unit of kW and kVA);

c) Maximum flow and usage rate of steam, and the maximum and minimum pressure values;

d) The mass and amount of steam required during sterilizer operation (please refer to Table C.2);

e) Amount of water for each cycle, maximum value and minimum value of required pressure for water supply, and the flow rate during low pressure;

f) Operating range of compressed air and the flow rate during low pressure;

g) The heat radiation power (W) of the sterilizer when the operating environmental temperature is (23 ± 2)^{o}C and during the opening and closing of the sterilizer door;

Note: When designing the ventilation system, the user should consider the heat radiation of the sterilised load.

h) The heat radiation power (W) in front of the sterilizer when opening and closing the door; and when the operating environmental temperature is (23 ± 2)^{o}C, the door can either be opened or closed;

i) Calculated Grade A sound intensity, and the round value of maximum impact noise index;

j) Description of sound intensity for any additional devices provided by the sterilizer manufacturer when these devices need to work together with the sterilizer;

k) Description of type of door and the space required for opening and closing the door;

Note: The loading and unloading of some items may need additional space.

l) Maximum flow of water discharge;

m) Maximum hardness value, pH value range and electric conductivity of the water supplied by the steam generator (please refer to Subsection C.1);

n) Handling instructions of the sterilizer packaging material;

o) Description of any necessary additional devices, e.g. independently installed air compressor;

p) Detailed description of the required medium supply facilities relating to pollutant discharge and ventilation;

q) Environmental type of sterilizer (please refer to Subsection 5.11.2);

r) Description of vacuum degree that meets the requirements of this Standard.

G.2.4 Before overall installation, the following information (please refer to Subsection G.1) should be provided:

a) Brief operating instructions;

b) User's manual, containing at least the following information:

— Scope of application;

— Type of load and package;

— Total mass;

— Designed pressure, allowed operating pressure and allowed temperature;

— Description of the useable sterilisation cycle;

— Introduction of the control, indication and recording devices;

— Introduction and setting of safety devices;

— Description of possible malfunctions;

— Cleaning guidelines;

— Introduction to the exclusive consumables and sterilizer accessories;

— Instructions for cleaning and appropriate detergents.

c) Dimensions and size of the pressure vessel;

d) Number of loadable sterilisation modules (an integer);

e) Description of sterilisation cycle, which should contain the following contents:

— Highest operating temperature;

— Relationship diagram showing the pressure change over time in sterilisation cycle;

— Record of temperature change over time of each standard test load applicable to the provided sterilizer during the corresponding running of sterilisation cycle;

— Key parameters of the sterilisation cycle (please refer to Subsection 5.7.1.3);

— Numerical range of key parameters of the sterilisation cycle;

— Position of reference measurement point (please refer to Subsection 5.7.1.4.)

Note: If required, the document certifying the relationship between the coldest point of useable space and the reference measurement point should be provided.

f) Introduction of safety parts (e.g. door interlock device);

g) Maintenance manual, which should include:

— Contents and implementation of maintenance and test;

— Electric diagram;

— Pipeline map;
— A complete list of spare parts;
— A list of tools exclusively for maintenance and detection;
— Quality assurance statement;
— A list of service company locations;
— Guideline of malfunction inspection;

h) Description on the disposal and handling of discarded sterilizers, consumables and accessories;

i) Leakage rate.

G.2.5 Other necessary information that is specified in Subsections G.2.3 and G.2.4 and applicable to the built-in steam generator should be provided.
