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Washer sterilizers for medical use

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Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Minister of Health, Labour and Welfare through deliberations at the Japanese Industrial Standards Committee according to the proposal of establishing a Japanese Industrial Standard from Japan Association of Medical Equipment Industries (JAMEI)/Japanese Standards Association (JSA), with a draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law.

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Washer sterilizers for medical use

1 Scope

This Japanese Industrial Standard specifies the basic requirement for a washer sterilizer that washes and sterilizes a used medical device (matters to be sterilized) polluted by organic matters, such as blood and necrotic cells, using the saturated vapour (that is directly available from the water in the chamber, or that is generated by a built-in steam generator, or that is available from an external steam source) in order to safely implement washing and post-processing of sterilization of a medical device for re-use. The washing methods include a hot-water immersion method, an ultrasonic irradiation method, a jet stream spray method, etc.

In addition, some sterilizers only sterilize a medical device (matters to be sterilized), using the saturated vapour, for the purpose of the secondary sterilization for re-use without washing a medical device.

A washer sterilizer covered in this Standard shall have a vessel²⁾ corresponding to the national pressure vessel structure standard¹⁾. However, this Standard excludes a washer sterilizer for biohazard and other types of sterilizers.

Notes¹⁾ It refers to the Safety Standard related to Construction Code for First Class Pressure Vessels specified by Industrial Safety and Health Law.

²⁾ It refers to First Class Pressure Vessel specified by Industrial Safety and Health Law, Enforcement Order, Article 1, Item 5.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. The most recent editions of the standards (including amendments) indicated below shall be applied.

JIS B 7505 *Bourdon tube pressure gauges*

JIS C 1010-1 *Safety requirements for electrical equipment for measurement, control, and laboratory use—Part 1: General requirements*

JIS C 1806-1 *Electrical equipment for measurement, control and laboratory use—EMC requirements*

JIS Z 8737-2 *Acoustics—Noise emitted by machinery and equipment—Measurement of emission sound pressure levels at a work station and at other specified positions—Survey method in situ*

ISO 11138-1 *Sterilization of health care products—Biological indicators—Part 1 : General requirements*

ISO 11138-3 *Sterilization of health care products—Biological indicators—Part 3 : Biological indicators for moist heat sterilization processes*

- ISO 11140-1 *Sterilization of health care products—Chemical indicators—Part 1 : General requirements*
- ISO 11140-3 *Sterilization of health care products—Chemical indicators—Part 3 : Class 2 indicators for steam penetration test sheets*
- ISO 11140-4 *Sterilization 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*
- ISO 11140-5 *Sterilization of health care products—Chemical indicators—Part 5 : Class 2 indicators for Bowie and Dick-type air removal tests*
- IEC 61010-2-040 *Safety requirements for electrical equipment for measurement, control and laboratory use—Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials*

3 Terms and definitions

For the purposes of this Standard, the terms and definitions given in **JIS C 1010-1** and the following apply.

3.1 pressure gauge

a meter that is attached to the chamber, the jacket, etc. of a washer sterilizer, and that measures the following pressure

The pressure in the chamber or the jacket is usually displayed in the unit of megapascal (MPa).

- A pressure gauge that measures the positive gauge pressure
- A vacuum meter that measures the negative gauge pressure
- A compound gauge that measures the positive and negative gauge pressures

3.2 pressure vessel

a vessel²⁾ that has a sealed space, that can withstand the internal pressure exceeding the atmospheric pressure, and that conforms to the Safety Standard of Construction Code for Boilers and Pressure Vessels¹⁾

3.3 medical device

any instruments, apparatus, implements, machines, appliance, implants, in-vitro reagents, calibrators, software, materials or other similar or related articles, intended by the manufacturer to be used, alone or in combination, for human body for one or more of the specific purpose(s) of

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- support of the anatomy, or investigation, replacement or modification a physiological process,

- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information for medical purposes by means of in-vitro tests of specimens derived from the human body,

and that does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but that may be assisted in its function by such means (see **JIS Q 13485**).

3.4 interlock

the means that prevent the chamber door or lid from opening accidentally when the pressure in the chamber exceeds the predetermined limit, and when water remains in the chamber, and/or the means that prevent water or steam from entering the chamber when the door or lid of the chamber is not locked

3.5 operating cycle

a complete set of processes carried out for washing and sterilization according to the predetermined sequence (see **IEC 61010-2-040**)

Example : The entire process that begins with closing the door or lid of a washer sterilizer, extends over the water supply, washing, air removal, sterilization, and exhaustion including natural cooling, finishes all the steps, and ends with opening the door or lid.

3.6 calculation control system

the system that predetermines the F -value (control value) against sterilization temperature, that stops totalizing the sterilization time when the calculated value of sterilization temperature and time becomes equivalent to a control value during use

Alternatively, the system that integrates the D -value, which is determined by the sterilization temperature and its retention time, and determines the sterilization temperature.

3.7 overkill method

the method that uses the biological indicator having the known D -value and the number of bacilli (for example, 10^6) and treats for $12D$ h, which ensures sterility assurance level of 10^{-6}

3.8 record/control apparatus

an apparatus that is designed to control parameters (temperature, etc.) and to always record parameters being controlled

3.9 emergency operation part

a switch (including the power switch) that enables a device to stop operation promptly, or an operation part to stop supplying steam and to ensure safety

3.10 chemical indicator

a system that clarifies one or more changes of predetermined variables, which is based on a chemical or physical change produced through interaction (exposure) with a sterilization process

3.11 calibration

a series of work that establishes the relation between the value indicated by instruments or the measurement system, or the value indicated by material measures or reference materials, and the value realized by a standard (see **JIS Z 8103**)

3.12 process

each processing step that constitutes the operating cycle

3.13 jacket

a mechanism that is attached around the chamber to maintain the internal temperature

3.14 gravity substitution type sterilizer

a steam sterilizer where the remaining air that prevents the elevation of the sterilization temperature in the chamber and the products to be sterilized is exhausted from outlet by the saturated steam pressure

3.15 steam generator

equipment that applies sufficient heat to water and changes it into steam

3.16 vacuum deairing type sterilizer

a steam sterilizer where the remaining air that prevents the elevation of the sterilization temperature in the chamber or the products to be sterilized is forcibly sucked and exhausted by a vacuum device before a sterilization process

A pulse deairing type is included.

3.17 control preset temperature

an arbitrary temperature which functions as the reference for operating a sterilizer control system to keep the chamber temperature within the required range near the selected sterilization (exposure) temperature

3.18 accuracy

the degree of agreement of a measured value with the true value, including trueness and precision of a measurement result (see **JIS Z 8103**)

3.19 totalizing method

the method where the sterilization time is added or subtracted for measurement by a sterilization timer that operates when the preset sterilization temperature is reached after normal change of the sterilization temperature

3.20 wash

an operation cycle where the water or the chemical processing substance, if necessary, is used to remove attached pollutants from the surface to be cleaned

3.21 challenge test pack

a test pack specified by supposing the products to be sterilized

It is used to evaluate the performance effectiveness of the operating cycle.

3.22 chamber

a vessel ²⁾ that forms a part of a sterilizer, in which the matters are washed and sterilized, that is shielded from environment with the door or lid, or that stores the matters to be washed and sterilized, and that forms a space for washing and sterilization

A chamber may have a single door or a double door.

3.23 *D*-value

action (exposure) time required to reduce the specific microbe group by one-logarithm reduction (90 %) under the predetermined setting conditions

3.24 electromagnetic compatibility (EMC)

the ability of equipment or a system that does not give the unacceptable electromagnetic disturbance to anything that is present in the environment where the said equipment or a system exists, and that can function satisfactorily in its electromagnetic environment

3.25 specially designated maintenance controlled medical device

medical devices whose potential risk is significant to the diagnosis, treatment or prevention of disease, without proper management, since these devices require expert knowledge and skill in maintenance, repair and other management

These devices are designated by the Minister of Health, Labour and Welfare after seeking the opinion of the Pharmaceutical Affairs and Food Sanitation Council.

3.26 half-cycle method

the method in which sterilization takes double the minimum time that kills all the biological indicators having the known *D*-value and the number of bacilli (for example, 10^6)

3.27 handle

a manual device that is used to open/close and/or to lock/unlock the door or lid of chamber

This term also applies to the flow controller of steam or water used by a sterilizer.

3.28 biological indicator

the microbe providing a defined resistance to the operating cycle, and the inoculated carrier within its primary pack ready for use containing that microbe

3.29 load

an article presented to the operating cycle, or its imitation (see IEC 61010-2-040)

3.30 saturated steam

steam that is in an equilibrium state between condensation and evaporation (steam in the state of saturation)

3.31 retention time

time during which the temperature of all the portions of load is kept within the sterilization temperature range

NOTE : It starts immediately after the equilibrium time. The length of retention time is related to the sterilization temperature.

3.32 Bowie Dick test

a test that monitors the air removal from the products being sterilized and the reliable steam penetration into the products being sterilized

A test uses, under the specified condition, the exclusive test pack and test sheet.

3.33 sterility assurance level (hereafter referred to as “SAL”)

probability of a viable microorganism being present on a product unit after sterilization

NOTE : SAL is usually expressed at 10^{-n} . When SAL is 10^{-6} , probability that one sterilized product remains nonsterile (with one viable microbe) is one-millionth or less.

3.34 sterilization

the validated operating cycle used to render a product free from viable microbe

NOTE : In the operating cycle, an exponential function expresses the essence of an inactivation action of the microbe. Therefore, existence of the viable microbe on all products can be expressed using probability. Although this probability can be decreased to a very low number, it is impossible to make it decrease to zero (see 3.33).

3.35 sterilization temperature

temperature that is reached and maintained during the retention time

3.36 sterilization timer

a mechanical or electrical equipment that controls the duration to maintain a sterilizer under the selected condition of sterilization

4 Requirements on a design

4.1 Design, structure, parts, and accessory of a washer sterilizer

4.1.1 Mechanical safety