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Hygienic Requirements for Low-Temperature Hydrogen Peroxide Gas Plasma Sterilizer

过氧化氢气体等离子体低温灭菌器卫生要求

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Hygienic Requirements for Low-Temperature Hydrogen Peroxide Gas Plasma Sterilizer

1 Scope

This Standard specifies the technical requirements, application range, precautions for use, inspection rules, inspection methods, marking and packaging, transportation and storage for the low-temperature hydrogen peroxide gas plasma sterilizer.

This Standard is applicable to low-temperature hydrogen peroxide gas plasma sterilizers for sterilizing medical devices, appliances and articles that are not resistant to humidity and high temperature.

2 Normative References

The following documents are essential to the application of this document. For the dated documents, only the versions with the dates indicated are applicable to this document; for the undated documents, only the latest version (including all the amendments) are applicable to this document.

GB/T 191 Packaging – Pictorial Marking for Handling of Goods

GB/T 1616 Hydrogen Peroxide for Industrial Use

GB/T 16886.5 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity

GB/T 16886.10 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization

GB/T 16886.11 Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity

GB 19192-2003 Hygienic Requirement for Contact Lens Care Solution

GBZ 159 Specifications of Air Sampling for Hazardous Substances Monitoring in the Workplace

GBZ/T 300.48 Determination of Toxic Substances in Workplace Air - Part 48: Ozone and Hydrogen Peroxide

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4.1.1.2 The sterilization program includes three stages: conditioning stage, sterilization stage and ventilation stage, which can be repeated and crossed.

4.1.2 Conditioning stage

4.1.2.1 The lower limit of the pressure of the sterilization chamber shall be no higher than the pressure specified by the manufacturer, and shall be no higher than 80Pa.

4.1.2.2 The temperature of the inner wall of the sterilization chamber shall be no less than 45°C at the end of the conditioning stage.

4.1.2.3 If plasma occurs, the maintenance time and input power shall comply with the manufacturer's provisions; the measured value of the maintenance time shall be no less than the minimum value specified by the manufacturer; and the measured error of the input power shall be within ±10%.

4.1.2.4 If there is purification, the concentration and dosage of hydrogen peroxide after purification shall comply with the manufacturer's provisions, and the error shall be within ±5%.

4.1.2.5 An alarm shall be issued when the sterilized items are too wet.

4.1.3 Sterilization stage

4.1.3.1 The temperature of the inner wall of the sterilization chamber shall be no greater than 60°C; the sterilization effect of the minimum temperature of the equipment shall be verified.

4.1.3.2 The maintenance time of the sterilization stage shall comply with the manufacturer's provisions; and the measured value of the maintenance time shall be no less than the minimum value specified by the manufacturer.

4.1.3.3 The sterilization pressure range should comply with the manufacturer's provisions.

4.1.3.4 The hydrogen peroxide concentration range during the sterilization stage shall comply with the manufacturer's provisions.

4.1.3.5 The concentration of hydrogen peroxide in the sterilization chamber should be monitored in real time.

4.1.4 Ventilation stage

4.1.4.1 The lower limit of the pressure of the sterilization chamber shall be no higher than the pressure specified by the manufacturer, and shall be no greater than 80Pa.

4.1.4.2 When plasma occurs, the maintenance time and input power shall comply with the manufacturer's provisions. The measured value of the maintenance time shall be

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4.5 Evaluation and monitoring of sterilization effect

Half cycle full load operation, aseptic growth.

4.6 Safety

4.6.1 Environmental exposure

4.6.1.1 The sterilizer shall be equipped with a hydrogen peroxide decomposition (filter) device and an alarm to prompt replacement function. The manufacturer shall specify its replacement cycle in the instruction manual.

4.6.1.2 In the workplace that meets the ambient ventilation conditions specified in the sterilizer instruction manual, the residual amount of hydrogen peroxide shall meet the 8h time-weighted allowable concentration (TWA) ≤ 1.5mg/m^3.

4.6.2 Biocompatibility

The items after sterilization shall be biocompatible with the human body.

4.6.3 Material compatibility

Compatibility evaluation is carried out after sterilization of metal and non-metal material instruments. The result shall be basically no corrosion; and the evaluation result is limited to tested materials. The appearance of the sterilized material shall not have obvious changes, such as color, shape, and cracks, etc.

5 Application Range

5.1 The low-temperature hydrogen peroxide gas plasma sterilizer is suitable for medical equipment, appliances and articles that are not resistant to humidity or high temperature.

5.2 The sterilizer shall not be used to sterilize the following objects:

a) Items that are not completely dry;

b) Articles or materials that absorb liquids;

c) Items made of cellulose-containing materials or any other items containing wood pulp;

d) One-end occluded cavity;

e) Liquid or powder;

f) Single-use items;

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Run the sterilizer in accordance with the instruction manual provided by the manufacturer to determine whether it satisfies 4.1.1.1 and 4.1.1.2.

8.1.2 Inspection in conditioning stage

8.1.2.1 Connect the pressure measuring device to the pressure test port of the sterilization chamber; run the sterilization cycle to determine whether it satisfies 4.1.2.1.

8.1.2.2 Use the temperature sensor to measure the inner wall of the sterilization chamber; and run the sterilization cycle to determine whether it satisfies 4.1.2.2.

8.1.2.3 Use a stopwatch to measure the time of plasma in generation stage; a dedicated power meter to measure the operating power of the plasma generator; run the sterilization cycle to determine whether it satisfies 4.1.2.3.

8.1.2.4 Run the sterilization cycle. After the purification stage is over, stop the operation of the device; disassemble the purification device; extract the hydrogen peroxide solution; measure the concentration according to the method specified in *Technical Standard for Disinfection* (2002 Edition), and determine whether it satisfies 4.1.2.4.

8.1.3 Inspection in sterilization stage

8.1.3.1 Use the temperature sensor to measure the inner wall of the sterilization chamber; run the sterilization cycle to determine whether it satisfies 4.1.3.1.

8.1.3.2 Run the sterilization cycle; use a stopwatch to measure the time in sterilization stage; and determine whether it satisfies 4.1.3.2.

8.1.3.3 Connect the pressure measuring device to the pressure test port of the sterilization chamber; run the sterilization cycle to determine whether it satisfies 4.1.3.3.

8.1.3.4 The hydrogen peroxide concentration sensor should be checked regularly to determine whether it meets 4.1.3.4.

8.1.4 Inspection in ventilation stage

8.1.4.1 Connect the pressure measuring device to the pressure test port of the sterilization chamber; run the sterilization cycle to determine whether it satisfies 4.1.4.1.

8.1.4.2 Run the sterilization cycle; use a stopwatch to measure the time of plasma in generation stage; use a dedicated power meter to measure the operating power of the plasma generator; and determine whether it satisfies 4.1.4.2.

8.1.4.3 Run the sterilization cycle. After the sterilization cycle is over, take the test equipment that has been processed by one sterilization cycle (the lumen of PTFE with an inner diameter of 1mm is 2m, and the lumen of stainless-steel tube with an inner diameter of 1mm is 500mm). Soak in 100mL of purified water for 1min; prepare

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Appendix A

(Normative)

Test Methods of Sterilization Effect

A.1 Method principle

This experiment uses the common hard mirror stainless steel lumen and soft mirror PTFE lumen as the simulated lumen to verify the sterilization effect of microorganisms. This test should use a seamless test lumen with openings on two ends, if there are seams, air tightness shall be ensured. A carrier stained with bacterial spores is placed in the center of the lumen, and grows aseptically through a half-period sterilization cycle. Using bacillus stearothermophilus spores as the index bacteria, the microbial sterilization effect was evaluated at the same time. All the tests were negative culture results, then the results were judged to be qualified.

A.2 Biological indicator

Bacillus stearothermophilus spores (ATCC7953).

A.3 Verification equipment

A.3.1 Carrier: Coat the spore suspension evenly on a stainless-steel test material with a diameter of 0.4mm and a length of 20mm~30mm; as long as it does not block the lumen after infection. The amounts of bacteria recovered from the positive spores of bacillus stearothermophilus shall be 1×10^6 CFU/carrier~5×10^6 CFU/carrier; use it after natural drying at room temperature.

A.3.2 Test lumen: A seamless test lumen with openings on two ends shall be used in this test. If there are seams, air tightness shall be ensured.

A.3.3 Stainless steel material lumens without seam: 10 pieces.

A.3.4 Teflon seamless lumens: 10 pieces.

A.3.5 TSB culture medium of bacillus stearothermophilus spores: 17.0g of dry powder tryptone, 3.0g of vegetable peptone, 5.0g of sodium chloride, 2.5g of dipotassium hydrogen phosphate, 2.5g of glucose, a total of 30g dissolved in 1L of distilled water; then prepare Tryptone Soy Broth (TSB) medium.

A.4 Operation procedures

A.4.1 The infected carrier is delivered to the center of the stainless-steel lumen; and 10 test samples are prepared. Place 10 test samples evenly in parallel in the instrument box; wrap them with double non-woven fabrics; and place them in the

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Appendix B

(Normative)

Biological Monitoring Method for Low-Temperature Hydrogen Peroxide Gas Plasma Sterilization

B.1 Biological indicator of bacillus stearothermophilus spores

The carrier shall have no adsorption effect on hydrogen peroxide; and the amounts of bacteria on each carrier shall reach 1×10^6 CFU. The resistance of the used spores to hydrogen peroxide gas shall be stable and qualified; and the used products shall satisfy the relevant national management required biological monitoring of luminal or non-luminal organisms monitoring package on the sterilization quality of the sterilizer.

B.2 Monitoring method of lumen biological monitoring package

When sterilizing luminal instruments, use a luminal biological PCD or a verification device equivalent to a luminal biological PCD for monitoring. The device shall be proven to be a sterilization challenge device that has the same or even stronger resistance than the luminal PCD. The lumen biological monitoring package shall be placed in the most difficult part to sterilize in the sterilizer (according to the suggestion from the manufacturer's instruction manual, away from the hydrogen peroxide injection port, such as the back of the lower instrument shelf in the sterilization chamber) for full-load sterilization. After the sterilization cycle is completed, immediately take out the luminal biological PCD from the sterilizer; and incubate at 56°C±2°C for 7 days (or follow the product instructions); and observe the culture results.

B.3 Monitoring method of non-luminal biological monitoring package

When sterilizing non-luminal instruments, use the non-luminal biological monitoring packages to monitor; Self-contained biological indicators shall be placed in Tyvek packaging bags. After sealed packaging, it is placed in the most difficult part to sterilize in the sterilizer (according to the suggestion from the manufacturer's instruction manual, away from the hydrogen peroxide injection port, such as the back of the lower instrument shelf in the sterilization chamber). Immediately after the sterilization cycle is completed, take out non-luminal biological monitoring package from the sterilizer; and incubate according to the self-contained biological indicator instructions; and observe the culture results.

B.4 Judgment of results

If the positive control group is culture-positive, the negative control group is culture-negative, and the experimental group is culture-negative, and it shall be judged as qualified for sterilization. If the positive control group is cultured-positive, the negative

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Appendix D

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Material Compatibility Test

D.1 Principle of the method

After the instruments are sterilized at low temperature by hydrogen peroxide gas plasma for many times, the surface of the instruments is not corroded. Measure the compatibility of the equipment materials after sterilization; and then determine the compatibility of hydrogen peroxide to the equipment during the sterilization process.

D.2 Sample preparation and operation procedures

D.2.1 Prepare samples with reference to 3.4.2 in *Technical Standard for Disinfection* (2002 Edition).

Metal sheet sample: round, diameter of 24.00mm, thickness of 1.00mm, passing through a small hole with a diameter of 2.00mm, the total surface area of about 9.80cm^2 (including the upper, lower, peripheral surface and the side of the small hole). The finish is 6. The raw materials are as follows:

Carbon steel	(see GB/T 700 for specifications)
Copper	(see GB/T 2059 for specifications)
Aluminum	(see GB/T 1173 for specifications)
Stainless steel	(see GB/T 1220 for specifications)

Rinse each sample with a neutral instrument washing solution; and then rinse thoroughly with distilled water to remove surface contaminants and residual cleaning agents. Dry each material with a non-woven cotton cloth. Blow dry with clean filtered air (or equivalent) to remove residual fibers on the sample. The samples are weighed, and each sample is weighed 3 times after the balance returns to zero, accurate to 0.1mg; and take the average value as the pre-test weight (when weighing, clean gloves shall be worn and the samples shall not be directly touched with hands). Wrap the test samples of each material in a single-layer Tyvek packaging bag to prevent bacteria from entering, and at the same time to ensure the infiltration of hydrogen peroxide.

D.2.2 Place the test sample flat in the sterilization instrument box, without covering the instrument box lid; and place the instrument box at the center of the upper layer of the sterilization chamber. Set the sterilization chamber temperature to the lowest allowable limit according to the manufacturer's operating instructions, and inject the maximum dose of hydrogen peroxide sterilant for full cycle sterilization.

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