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Vacuum-Assisted Boiling Washer-Disinfector

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Preface

This document is drafted in accordance with the *Directives for standardization — Part 1: Rules for the structure and drafting of standardizing documents* (GB/T 1.1—2020).

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Vacuum-Assisted Boiling Washer-Disinfector

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1 Scope of application

This document specifies the classification, requirements, test methods, inspection rules, markings, packaging, nameplates, instructions, transportation, and storage of vacuum-assisted boiling washer-disinfectors.

This document applies to vacuum-assisted boiling washer-disinfectors (hereinafter referred to as "washer-disinfectors"), used for decontamination, cleaning, disinfection, and drying of medical devices.

This document does not apply to washer-disinfectors cleaned using spray or ultrasonic cleaning technology.

2 Normative references

The following normative documents contain provisions, which, through reference in this text, constitute provisions of this document. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. For undated references, the latest edition of the normative document (including any amendments) referred to applies.

Packaging-Pictorial Marking for Handling of Goods (GB/T 191)

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

Safety requirements for electrical equipment for measurement, control, and laboratory use-Part 4: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials (GB 4793.4)

Pipe threads with a 55° thread angle where pressure-tight joints are not made on the threads (GB/T 7307)

Environmental requirements and test methods for medical electrical equipment (GB/T 14710)

Thermocouples—Part 1: EMF specifications and tolerances (GB/T 16839.1)

Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements (GB/T 18268.1)

Industrial platinum resistance thermometers and platinum temperature sensors (GB/T 30121)

Evaluation method of endoscopic disinfection effect (GB/T 38497)

Central sterile supply department (CSSD) Part II: standard for operating procedure of cleaning, disinfection, and sterilization (WS 310.2)

Test methods of disinfection products (WS/T 10009)

Washer-disinfectors—Part 1: General requirements and tests (YY/T 0734.1—2018)

Technical Standard for Disinfection (2002 Edition) [Ministry of Health P.R.China (Document No. 282, Wei Fa Jian Fa [2002])]

3 Terms and definitions

The terms and definitions defined in the standard (file No. YY/T 0734.1—2018) and the following apply to this document.

3.1 Vacuum-assisted boiling washer-disinfector 减压沸腾清洗消毒器

A device that integrates vacuum-assisted boiling, liquid phase boiling, vapor phase boiling, pressure restoration cleaning, and vacuum-assisted liquid phase boiling disinfection, without the use of other cleaning technologies (such as ultrasonic cleaning), to achieve cleaning, disinfection, and drying of medical devices by boiling water at low temperatures.

3.2 Vacuum-assisted boiling 减压沸腾

Air is mechanically (using a vacuum pump) extracted from the cleaning chamber to create a low-pressure environment, causing the liquid to boil and vaporize at a low temperature and accelerating the boiling process.

3.3 Liquid phase boiling 液相沸腾

The liquid is boiled at a set vacuum and low cleaning temperature.

3.4 Vapor phase evaporation/boiling 气相沸腾

The liquid is boiled at a set vacuum when it has not reached the boiling temperature.

3.5 Pressure restoration/vacuum release 平压

It introduces air into the cleaning chamber that has been under low pressure (negative pressure) to restore it to normal atmospheric pressure.

3.6 Vacuum-assisted liquid phase boiling disinfection 减压液相沸腾消毒

During the disinfection process, vacuum-assisted boiling and liquid phase boiling are used to improve the uniformity of the disinfectant temperature inside the chamber, achieving disinfection.

4 Composition and classification

4.1 Composition

The washer-disinfector consists of a main body (including a single or multiple working chambers, a pre-installed hot water tank, a vacuum-assisted boiling system, a liquid-phase boiling system, a vapor-phase boiling system, a disinfection system, a drying system, and a control system), a load rack, a basket, and a trolley.

4.2 Classification

According to the heating method, washer-disinfectors are divided into electric heating and steam heating washer-disinfectors. According to the structure, washer-disinfectors are divided into single-chamber and multi-chamber washer-disinfectors.

5 Performance requirements

5.1 General requirements

5.1.1 Materials

a) The materials used in the washer-disinfector and its accessories shall be resistant to chemical, mechanical, and thermal loss during normal operation as specified by the manufacturer.

b) Components in contact with the load shall be made of corrosion-resistant and wear-resistant materials.

c) All components in contact with water, chemicals, and/or steam shall be resistant to the corrosive action of these substances, or the instructions shall specify the types of chemicals that cannot be used.

d) The effects of galvanic corrosion, vibration, and uneven expansion at the junctions of different metal materials shall be considered.

e) The combination of materials used shall be compatible with each other and suitable for the process variables.

f) Components for holding and dispensing chemicals shall be made of materials that do not react with chemicals such as acids, alkalis, and oxidants.

5.1.2 Appearance

The external surface of the washer-disinfector shall be smooth and easy to clean. All maintainable parts and surfaces shall not have sharp edges or burrs.

5.2 Normal operating conditions

5.2.1 Tap water pressure: 0.15 MPa~0.3 MPa.

5.2.2 Steam pressure: 0.3 MPa~0.6 MPa.

5.2.3 Power supply: 380 VAC±10%, 50 Hz.

5.2.4 Ambient temperature: 5℃~40℃.

5.2.5 Relative humidity: ≤80%.

5.2.6 Atmospheric pressure: 70 kPa~106 kPa.

5.2.7 Purified water pressure: 0.15 MPa~0.3 MPa.

5.2.8 Compressed air pressure: 0.5 MPa~0.8 MPa.

5.2.9 Water for terminal rinsing and moist heat disinfection: purified water with a conductivity of ≤ 15 μS/cm (25℃).

5.3 Structure

5.3.1 General requirements

a) The washer-disinfector shall allow an operator to perform routine tasks without tools and facilitate component maintenance and general cleaning, and the panels shall be easy to assemble and disassemble.

b) A load rack shall be provided to fix the load during cleaning and disinfection. If an interchangeable load rack or basket is provided, they shall be installable and removable without tools. The load rack shall be able to clean and disinfect during normal operating cycles and the self-draining shall not be obstructed.

c) A floor-mounted washer-disinfector shall provide measures to adapt to uneven floors, al-

lowing a maximum horizontal tilt of ∠5°.

d) During normal operation, the chamber, pipelines, and related components shall not leak.

e) The washer-disinfector shall ensure that the load is not re-contaminated or that microorganisms (or bacterial endotoxins) are not transferred from the washer-disinfector to the load during disinfection and subsequent steps.

5.3.2 Working chamber

5.3.2.1 The chamber of the washer-disinfector, which may contain liquid during operation, shall have a liquid level control device and self-draining function. Residual liquid in the washer-disinfector shall only flow to the drain outlet.

5.3.2.2 The over-temperature protection device shall be manually resettable.

5.3.2.3 The operating pressure of the chamber shall not exceed atmospheric pressure by 20 kPa, and it shall have an over-pressure protection device. When the chamber pressure exceeds atmospheric pressure by 20 kPa, it shall automatically release pressure. No leakage shall occur before the over-pressure protection device is triggered.

5.3.3 Door

5.3.3.1 The single-chamber washer-disinfector may have one door for loading and unloading, or two through-type doors, one for loading and the other for unloading. The multi-chamber washer-disinfector may have a loading door, an unloading door, and one or more partition sealing doors.

5.3.3.2 The door seal shall prevent fluid from leaking through the sealing port during the operating cycle, for example, by using a sealing gasket or a labyrinth (tortuous path) system. Methods for cleaning and replacing the door sealing gasket shall be provided. The structure and opening method of the door shall ensure that residual water is drained when the door is opened.

5.3.3.3 From the start to the end of the operating cycle, the loading and unloading doors of a single-chamber washer-disinfector shall not be unlocked and opened. For the multi-chamber washer-disinfector, the unloading door and the adjacent partition sealing door shall not be unlocked and opened simultaneously.

5.3.3.4 If a fault occurs during the operating cycle, the fault shall be indicated, and direct access to the load by opening the door shall be prevented.

5.3.3.5 For equipment that uses a door-locking method to prevent access to the load, a special key, code, or tool shall be used to unlock the door and access the load.

5.3.3.6 A special device shall be installed to securely fix the door in the open position.

5.3.3.7 If the door is not properly locked, the operator shall not be able to start the operating cycle. The control system may provide an override control for maintenance purposes.

5.3.3.8 If the door drive mechanism fails, the door shall be opened manually.

5.3.3.9 The door shall have a safety switch to prevent obstacles or hand pinching when being closed. It shall automatically stop and display an alarm when encountering any obstacle.

5.3.3.10 The start control of the operating cycle shall only be located at the loading end of the washer-disinfector. After the loading door is closed and locked, the unloading door shall not be opened until the completion of the first operating cycle of the washer-disinfector.

5.3.3.11 In the event of a fault, only the loading door and the partition sealing door can be opened.

5.3.3.12 The operator shall not be able to operate the washer-disinfector from one end to open or close the door at the other end. Additionally, under normal operating conditions, all doors of the washer-disinfector shall not be opened simultaneously to prevent free airflow through the chamber.

5.3.3.13 Visible indicators shall be provided at both ends of the washer-disinfector to indicate the progress of the cycle.

5.3.3.14 For the multi-chamber washer-disinfector, when the unloading door is unlocked, the adjacent partition sealing door shall remain locked until the unloading door is locked again.

5.3.3.15 Manual controls of the doors shall comply with the following requirements.

a) Instructions for manually locking the door

shall be provided to the operator. Additionally, if the unlocking process is not the reverse of the locking process, instructions shall be provided to guide the operator on how to manually unlock the door.

b) If necessary, the instructions shall be clearly displayed on the door, handle, or handwheel. These instructions shall also be clearly displayed on the front panel or operator control panel next to the door.

5.3.3.16 Internal doors and maintenance ports, if the internal door is installed between adjacent parts of a multi-part washer-disinfector and the maintenance port opens outward, shall prevent the operator from opening them without tools if opening the door and maintenance port would have harmful effects on the load or environment.

5.3.3.17 The door opening and closing may be:

a) controlled by a touch screen;

b) controlled mechanically, such as by foot pedal;

c) both.

5.3.3.18 An observation window may be installed on the door. The form and number of the observation window may vary as long as sealing and door operation performance are ensured.

5.3.4 Pipes, fittings, and valves

5.3.4.1 The manufacturing, installation, and/or operation of pipelines, pumps, valves, and fittings shall ensure that all residual liquids flow toward the drain outlet.

5.3.4.2 The temperature and pressure of valves connected to the chamber during the operation shall not exceed 80% of the valve's rated value.

5.3.5 Water supply

5.3.5.1 The water quality requirements for each step shall be clearly defined. If necessary, measures shall be taken to periodically or continuously monitor whether the water quality in each step complies with the requirements.

5.3.5.2 The monitoring function can be provided by equipment other than the washer-disinfector, installed in the water supply system.

5.3.5.3 The design operating conditions for the washer-disinfector shall be one of the following:

a) supplied by potable water; or

b) supplied through water treatment equipment that is fed by potable water.

Note: Water treatment equipment may include softening devices, deionization devices, or reverse osmosis apparatus (if necessary).

5.3.6 Ventilation system

5.3.6.1 The ventilation of the washer-disinfector shall comply with the following requirements:

a) be discharged into the atmosphere outside the building;

b) be discharged indirectly into the drainage system through a condenser; and

c) be discharged into the work area.

Note: If it is discharged into the work area, a condenser or microbial filter may be required.

5.3.6.2 The ventilation system shall ensure that the pressure inside the chamber can be fully discharged through the air vent.

5.3.6.3 If a condenser is used for indirect ventilation, the trap seal between the chamber and the drain outlet shall not be broken.

5.3.6.4 When it is necessary to connect an air duct, the connection shall ensure that no condensate is discharged onto the external surface of the washer-disinfector. For example, it shall be internally connected to the exhaust sleeve above the washer-disinfector.

5.3.6.5 Any condensate discharged from the piping system shall not contact the load.

5.3.7 Drainage system

5.3.7.1 The drain trap shall include the following:

a) a trap seal (usually with a depth of not less than 50 mm); and

b) a trap (which can be disassembled for cleaning or equipped with a port for cleaning).

5.3.7.2 After the end of an operating cycle, if the water level in the chamber remains above the lowest sealing point of the chamber door, the control system shall indicate a fault.

5.3.8 Air filter

5.3.8.1 When it is required to introduce air into the disinfection chamber, the air shall enter through an

air filter. The air filter shall be installed outside the disinfection chamber in a location accessible and easy to remove for cleaning, inspection, and replacement, and shall be kept dry.

5.3.8.2 The air filter shall remove particles with a diameter of not less than 0.30 μm (≥0.30 μm) with a filtration rate of not less than 99.5%.

5.3.9 Port validation

5.3.9.1 An access port shall be provided to facilitate the introduction of a temperature sensor into the chamber. This port shall be a straight connecting sleeve and installed at a location convenient for operation. The inner diameter of the straight connecting sleeve shall be (10±0.5) mm, the external thread complies with the standard (file No. GB/T 7307), the length be (15±0.5) mm, and there be a relief groove with a width of (3±0.5) mm in front of it (Figure 1).

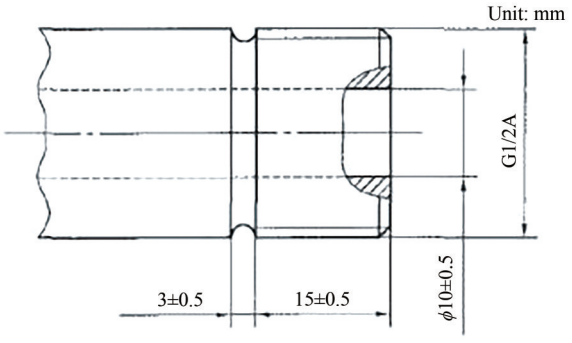

Figure 1 Access port for wires of temperature sensor

5.3.9.2 The connecting sleeve, together with its O-ring seal or flat washer, shall be closed with a standard cap and insulated and mechanically sealed.

5.3.9.3 The installation position of the connecting sleeve shall allow liquid to drain away under gravity.

5.3.10 Pre-installed hot water tank

5.3.10.1 The washer-disinfector shall prevent secondary contamination or the transfer of microorganisms (or bacterial endotoxins) from the washer-disinfector to the load during the disinfection and subsequent steps. This can be achieved through the following.

a) Ensuring that the pipe in contact with the load and the chamber during the normal operating cycle can be cleaned and disinfected.

b) Providing a separate self-cleaning and disinfection cycle.

5.3.10.2 The water tank for storing process water in the washer-disinfector shall comply with the following requirements.

a) Be self-draining.

b) Be installed in a position that allows cleaning under the condition of only removing removable panels and fasteners.

c) Automatically drain when the washer-disinfector is powered off or be equipped with a manual drainage system operated by the user.

d) Be equipped with an overflow warning tube or equivalent measures to alert the operator in case of tank overflow.

5.3.10.3 Since the water supply can be contaminated with large particles, the tank shall have an easily cleanable removable filter.

5.3.10.4 If a heater is installed, it shall be removable for replacement or easy cleaning.

5.3.10.5 When heating water, the heating temperature shall be controlled within the specified range.

5.3.10.6 If a terminal rinse tank is built-in, it shall comply with the following requirements.

a) The water temperature in the tank shall be maintained at not less than 65℃.

b) The rinse water shall be automatically disinfected before the rinse step.

5.3.10.7 The quality of the terminal rinse water in the tank shall comply with the requirements in Section 4.3.9.

5.3.11 Vacuum-assisted boiling system

5.3.11.1 The distribution of the pipes shall ensure that cleaning water cannot be extracted.

5.3.11.2 Valves shall be installed in the pipes.

5.3.11.3 All installed pipes shall be removable, with connecting ports, screws, or other fittings at the ends, and all internal and external surfaces shall be easy to clean.

5.3.11.4 All fittings to be disassembled by the user shall be designed to withstand at least 250 disassembly and assembly cycles. All fittings shall prevent misalignment during assembly or reassembly.

5.3.11.5 The operating noise of the washer-disinfector

shall not exceed 80 dB(A).

5.3.11.6 The minimum vacuum shall be ⩽−90 kPa, the rated operating vacuum be ⩽−80 kPa, and the pumping speed of the vacuum pump be ⩾13 L/s.

5.3.11.7 The system shall ensure that the cleaning solution can boil when setting the cleaning temperature (45℃~90℃).

5.3.11.8 When the cleaning solution does not achieve liquid phase boiling, including other steps, vapor phase boiling can be achieved, with an impact strength of ⩽8 kPa/s.

5.3.11.9 During the cleaning process, to prevent damage to the instruments being cleaned, only vacuum-assisted boiling, liquid phase boiling, vapor phase boiling, and pressure restoration, and their cross-application shall be used. No other devices shall be used to accelerate the boiling of the cleaning solution.

5.3.11.10 During liquid phase boiling and vapor phase boiling, ultrasonic devices or functions shall not be introduced in the prevention of damaging the precise medical instruments being cleaned.

5.3.11.11 During liquid phase boiling and vapor phase boiling, no docking device shall be required to achieve qualified cleaning and disinfection effects.

5.3.11.12 During the cleaning process, the pressure and temperature changes of the vacuum-assisted boiling system shall be displayed.

a) The cleaning temperature shall be controlled above the design temperature, not exceeding 5℃.
b) The design cleaning temperature range shall be 45℃~90℃.
c) The cleaning pressure shall not exceed −80 kPa.
d) The frequency of vacuum-assisted boiling per minute shall be not less than 2.

5.3.12 Liquid phase boiling system

5.3.12.1 It shall be located at the bottom of the working chamber.

5.3.12.2 It shall keep the cleaning solution boiling continuously at the set pressure and temperature, with a temperature range of 40℃~90℃.

5.3.12.3 It shall generate a large number of dense bubbles during the boiling process.

5.3.13 Vapor phase boiling system

5.3.13.1 It shall be located at the bottom of the working chamber.

5.3.13.2 It shall cause the cleaning solution to rapidly and violently churn.

5.3.13.3 It shall automatically discharge the cleaning solution from the vapor phase boiling system in the chamber after drainage.

5.3.13.4 The boiling air intake rate shall be adjustable, with an air return rate of ⩽8 kPa/s.

5.3.14 Disinfection system

5.3.14.1 During the disinfection maintenance step, the temperature shall be maintained within 0℃ ~ +5℃ of the disinfection temperature.

5.3.14.2 The chamber containing the load shall be able to disinfect by an automatic controller.

5.3.14.3 The disinfection system shall have the function of boiling the disinfection liquid, with both methods of soak disinfection and vacuum-assisted liquid phase boiling disinfection available.

5.3.15 Self-cleaning and disinfection system

5.3.15.1 There shall be a self-cleaning and disinfection program to ensure that the washer-disinfector does not accumulate contaminants from instruments, and self-cleaning and disinfection shall be performed after the washer-disinfector is interrupted for maintenance, repair, or testing.

5.3.15.2 The self-cleaning and disinfection program shall ensure that all chambers, pipes, and tanks of the washer-disinfector are cleaned and disinfected.

5.3.15.3 The self-disinfection program shall be run in an unloaded state; the A0 value for moist heat disinfection shall be at least 600.

5.3.16 Drying system

5.3.16.1 It shall include hot air drying and vacuum drying, with a filtration device to ensure that the gas entering the chamber is clean.

5.3.16.2 For vacuum drying, continuous vacuum drying or impulse vacuum drying is available, with a pressure range of −90 kPa~0 kPa.

5.3.16.3 Hot air drying shall have an impulse drying function, with a pressure range of 0 kPa~20 kPa

and an air pressure of ⩽10 kPa.

5.3.16.4 There shall be an over-pressure protection device for the chamber in the drying step.

5.3.16.5 There shall be an over-temperature protection device for the chamber in the drying step.

5.3.17 Control system

5.3.17.1 An automatic controller shall be provided.

5.3.17.2 The parameters related to each step of the operating cycle can be preset through the control system.

5.3.17.3 The automatic controller shall detect whether the preset process variables are within the specified threshold range.

5.3.17.4 The preset values for each process variable in the automatic controller shall be specified to comply with the specified performance requirements.

5.3.17.5 The automatic controller shall ensure that each operating cycle is repeatable within the threshold range specified by the manufacturers and shall continuously maintain the temperature within the specified disinfection temperature range for the specified time.

5.3.17.6 During the operating cycle, the preset variables shall not be adjusted.

5.3.17.7 Access to the control system (including setting process variables) shall not require disassembly or movement of the control device, and shall only be available using a special key, password, or tool.

5.3.17.8 The preset operating cycles can be launched using a keyboard, password, or switch.

5.3.17.9 For maintenance, testing, and emergency purposes, measures can be taken to run the automatic controller using a manual step-by-step method. This manual method shall be launched using a special key, password, or tool different from those specified above.

5.3.17.10 When manual control is used for maintenance, testing, or emergency purposes, the automatic program shall be shut down automatically.

5.3.17.11 Any preset and adjustable control devices shall be installed behind a locked panel or adjusted using a special key, password, or tool.

5.3.17.12 The manual operation program shall only allow to launch one step at a time in sequence.

5.3.17.13 The cleaning temperature, disinfection temperature, and disinfection time shall be able to preset, and their adjustments shall be available using a key, password, or tool.

5.3.18 Override control of automatic control

5.3.18.1 The override control performed by the operator on the control panel shall comply with the following requirements.

a) Only be available in the event of a fault.

b) Allow manual control of the door.

c) Only be available using a key, password, or tool different from those required for normal operating cycle.

5.3.18.2 When override control is provided for testing purposes and can only be performed by trained or authorized personnel, its operation shall comply with the following requirements.

a) Require using a special key, password, or tool different from those specified in Sections 5.3.17.7, 5.3.17.11, and 5.3.18.1c); and

b) Be independent of whether a fault has occurred.

If the special key, password, or tool specified in a) is used, the trained or authorized personnel shall be able to observe the instruments of the washer-disinfector at the same time.

5.3.19 Dosing system

5.3.19.1 A dosing system shall be provided to control the dosage of all necessary chemicals.

5.3.19.2 Each dosing system shall provide a method for adjusting the dosage. A special key, password, or tool shall be used for adjustment. The adjustment method can be manual or automatic.

5.3.19.3 Each dosing system shall be controlled by the automatic controller to introduce chemicals in each step of the operating cycle of the washer-disinfector.

5.3.19.4 Each dosing system shall provide a direct or indirect method to determine whether the amount and time of introduction during the operating cycle are within the range set by the automatic controller program. If the minimum required amount cannot

be introduced, a fault shall be indicated.

5.3.19.5 The control accuracy and repeatability of the amount provided by each dosing system shall be specified.

5.3.19.6 A system shall be provided to indicate whether there are sufficient chemicals to complete the next cycle.

5.3.19.7 Multiple cleaning liquid level control systems shall be provided to facilitate adjustment of the load volume. When different load volumes are selected, the program shall automatically adjust the dosage of chemicals.

5.3.19.8 The chemical introduction amount during the process (presented in Sections 5.3.19.2, 5.3.19.4, and 5.3.19.5) shall be able to adjust using a key, password, or tool, with an accuracy of ±5%.

5.3.20 Load temperature protection

5.3.20.1 If the over temperature than the preset may damage the item processed by the washer-disinfector, one or more over-temperature protection devices shall be provided to protect the load from exposure to over temperatures that could cause damage to the temperature-sensitive instruments being processed.

5.3.20.2 The over-temperature protection device shall be manually resettable.

5.3.20.3 When used to limit the temperature of the medium in contact with the load, the over-temperature protection device shall activate at a temperature not exceeding the maximum temperature provided by any temperature control or temperature limiting device by +5℃.

5.3.20.4 For the washer-disinfector that uses steam to heat the water tank and/or perform moist heat disinfection, the chamber shall have a protection function to prevent the pressure from rising above the design operating pressure of the chamber. For the chamber designed to operate at atmospheric pressure, the operating pressure shall not exceed atmospheric pressure by 20 kPa.

5.3.21 Process temperature control

5.3.21.1 The process shall comply with the following requirements.

a) During the holding time of the disinfection step, the recorded surface temperature of the load and load rack shall be at 0℃~+5℃ of the disinfection temperature.
b) During the holding time of each other step (excluding disinfection and drying steps), the recorded surface temperature of the load and load rack shall be within ±5℃ of the design temperature for the corresponding step.
c) Except as otherwise specified in this document, the temperature curve values obtained during the temperature control step of the operating cycle shall be within ±2.5℃.
d) The holding time determined based on the temperature measured on the load surface shall not be less than the specified disinfection step time (or the specified A0 value).
e) During the holding time of the disinfection step, the temperature measured on the surface of the load and load rack shall be within the specified disinfection temperature range (or reach the specified A0 value).
f) The temperature displayed on the chamber temperature indicating device and/or recorder shall be within ±2℃ of the temperature measured by the temperature sensor.
g) During the holding time of the disinfection step, the temperature measured on the surface of any load at any time shall not vary by more than ±2℃ compared to the average temperature measured during the same step; and at the same time, the temperature difference between any loads shall not exceed 4℃.

5.3.21.2 The temperature of the inner wall of the chamber during the entire process shall comply with the following requirements.

a) During the holding time of the disinfection step, the recorded surface temperature of the chamber shall be at 0℃～+5℃ of the disinfection temperature.
b) During the holding time of other steps (excluding the disinfection step), the recorded surface temperature of the chamber shall be within ±5℃ of the design temperature for the corresponding step.
c) During the entire holding time of the disin-

fection step, the temperature values indicated and recorded by the washer-disinfector shall be within ±2℃ of the values measured by the temperature sensor at the reference detection point.

d) Except as otherwise specified in this document, the temperature curve values obtained during the temperature control step of the operating cycle shall always remain within ±2.5℃.

5.3.22 Instruments and controls

5.3.22.1 Each instrument and indicator shall be labeled with its function. If it is used for temperature measurement, the sensor location shall be indicated. If an instrument is connected to multiple sensors, the values of all currently active sensors shall be displayed on the instrument.

5.3.22.2 The identification information of the sensor shall allow the operator to understand the meaning of the instrument reading, such as "Pre-rinse temperature".

5.3.22.3 The characters on each indicator or display shall be clearly visible from 0.25 m~1.0 m.

5.3.22.4 When used for calibration adjustment, the instrument shall be adjustable without disassembly. The adjustment device shall be protected, for example, by a cover or fixed screws in prevention of accidental adjustment.

5.3.22.5 At least one temperature sensor shall be installed in a pre-determined position to represent the lowest temperature position of the load. This ensures that all loads requiring disinfection and all surfaces of the chamber reach the disinfection temperature within the required time.

5.3.22.6 If process validation is performed,

a) during the operating cycle, a method shall be provided to independently validate the calibrated instruments and process control instruments;

b) if the temperature sensor is connected to the controller, temperature indicating device, or recorder, the temperature difference between all these temperatures shall not exceed 2℃ during the holding time of any step. This can be achieved by comparing the recorded and indicated temperatures, or by displaying an error at the end of the cycle; and

c) the sensor can be placed in the water that flows to the chamber, in the chamber water tank, or in the water discharged from the chamber.

5.3.22.7 The following indicators shall be located at the load of the washer-disinfector:

a) "Cycle in progress" indicator;

b) "Fault" indicator;

c) Timer or cycle counter that cannot be reset by the user;

d) "Cycle end" indicator;

e) "Chemical agent insufficient" indicator; and

f) temperature indicator that at least displays the temperature at the reference detection point during the cleaning, disinfection, and drying steps of an operating cycle. Additionally, an audible alert device can be provided, and the alert sound can be manually silenced.

"Cycle end" indication is not applicable to continuous operation of the washer-disinfector. Additionally, an audible alert device can be provided, and the alert sound can be manually silenced.

5.3.22.8 The following instruments and indicators shall be located at the unload of the washer-disinfector:

a) "Cycle in progress" indicator;

b) "Cycle end" indicator; and

c) "Fault" indicator.

Note[1]: "Cycle end" indication is not applicable to continuous operation of the washer-disinfector. Additionally, an audible alert device can be provided, and the alert sound can be manually silenced.

Note[2]: In systems that control disinfection time or temperature, a fault indication shall be provided if any sensor fails.

5.3.23 Temperature indicating device

5.3.23.1 The temperature sensor shall be the Class B platinum resistance sensor as specified in GB/T 30121, or other devices validated to have equal or

better accuracy.

5.3.23.2 The chamber temperature indicating device of the washer-disinfector shall comply with the following requirements.

a) Be either digital or analog;
b) Use degrees Celsius (℃) as the unit;
c) Have a range not narrower than 5℃~99℃;
d) Have an accuracy of at least ±1℃ within the range of 10℃~99℃;
e) For analog instruments, the graduation shall not exceed 1℃;
f) For digital instruments, the resolution shall be at least 1℃;
g) When used for control functions, it shall have sensor fault protection to ensure safety in case of fault;
h) The error caused by ambient temperature changes shall not exceed 0.08℃/℃; and
i) Allow on-site adjustment using a special key, password, or tool.

Note: A bimetallic thermometer is unavailable to these performance requirements.

5.3.24 Pressure indicating device

The pressure-indicating device shall comply with the following requirements.

a) Be either digital or analog.
b) Use kilopascals (kPa) as the unit.
c) Have an accuracy of at least ±5 kPa.
d) Have a range that ensures the expected maximum operating pressure does not exceed 80% of the full scale.
e) For analog instruments, the graduation shall not exceed 20 kPa.
f) For digital instruments, the resolution shall be at least 1 kPa.
g) When used for control functions, it shall have sensor fault protection to ensure safety in case of fault.

Allow on-site adjustment using a special key, password, or tool.

5.3.25 Time indicating device

5.3.25.1 The accuracy and repeatability of the process control timer shall be better than the expected time interval value.

5.3.25.2 The time indicating device shall comply with the following requirements.

a) Use seconds (s) or minutes (min) as the unit.
b) Have an accuracy of ±2.5% for time below 5 minutes and an accuracy of ±1% for time over 5 minutes.
c) Allow on-site adjustment using a special key, password, or tool.

5.3.26 Operating cycle indicating device

5.3.26.1 An intuitive indication of the current step in which the operating cycle is being shall be provided.

5.3.26.2 The operating cycle counter or timer shall display at least 5 digits, and the user shall not be able to reset it.

5.3.27 Recording device

5.3.27.1 Sensors, and/or signal amplifiers, and/or analog-to-digital (A-to-D) converters that provide cycle control recording devices with recorded information shall provide the same information to the control system.

5.3.27.2 The recording device shall be able to record critical process variables of the operating cycle.

5.3.27.3 The recording device shall be able to generate permanent records. The generated records shall be preserved under normal operating environmental conditions, and the records shall be able to be stored for a long time and be clearly legible. Thermal paper shall not be used to record information.

5.3.27.4 The printed data shall fully reflect any deviations beyond the allowable tolerance range.

5.3.27.5 The recording device shall be able to make on-site adjustments using a special key, password, or tool for calibration purposes.

5.3.28 Fault indication

5.3.28.1 If the value of a process variable exceeds the specified limit, or if a fault in the medium system affects these variables from reaching normal values, the automatic controller shall comply with the following requirements.

a) Indicate that a fault has occurred (an audible alert device that can be silenced may also

be provided).

b) Indicate in which step of cleaning or disinfection the fault occurred or the nature of the fault.

5.3.28.2 After a fault has been indicated, the automatic controller shall be able to terminate the operating cycle of the washer-disinfector without causing a risk. Any user intervention shall require a special key, password, or tool. The visual fault information shall be displayed at least until the door lock protection is released using a special key, password, or tool.

5.3.28.3 After a fault occurs in a continuous processing of the washer-disinfector, any load that does not comply with the processing requirements shall be removed from the loading end of the washer-disinfector.

5.3.28.4 If a printer is provided, it shall be able to print fault indication details, and the content shall be easy to identify.

5.3.29 Load rack and basket

5.3.29.1 If a support device and/or device for transporting the load into and out of the chamber are provided, they shall comply with the following requirements.

a) The load shall be fully supported and fixed. During the operating cycle, it shall remain within the available space of the chamber.

b) The load rack shall comply with the following requirements.

i. Remain in the chamber, and the mechanical mechanism shall only be released when the transport system is in place; or

ii. Be equipped with a positioning device that maintains the rack stable when the rack is partially pulled out. If further pulling out of the load is required, the device shall be released. The requirements for pulling out and maintaining the stability shall be clearly defined.

c) Under full load conditions, when operated according to the instructions, the force applied by the operator, whether directly or using the mechanical device provided by the equipment, to unload from the chamber shall not exceed 250 N.

5.3.29.2 The load shall not damage the chamber when loading and unloading.

5.3.29.3 The load rack shall be made of durable, corrosion-resistant materials and shall be able to withstand the environmental conditions of the chamber without damage.

5.3.29.4 The load rack shall ensure that the preset process variables are achieved, and allow water to drain freely from the load, as well as allow water and/or steam to fully contact the load.

5.3.29.5 The load rack shall be prevented from misplacement.

5.3.29.6 The load rack shall not affect the cleaning and disinfection of the load. The load rack or basket for placing instruments shall ensure that the entire instrument remains submerged in the cleaning step.

5.3.29.7 The load rack shall run smoothly and flexibly on the inner chamber rails and shall be able to withstand a weight of 10 kg without significant deformation.

5.3.29.8 If necessary, a method shall be provided to facilitate the correct placement of the load during chamber cleaning.

5.3.29.9 When processing lumened instruments and/or powered devices, a protective load rack shall be provided to ensure that all devices are fully cleaned during the process.

5.3.30 Trolley

5.3.30.1 The trolley shall be aligned easily with the washer-disinfector by an operator during loading and unloading.

5.3.30.2 The trolley shall have a device to collect residual liquid from the load and prevent it from dripping onto the floor. This device shall be removable for cleaning.

5.3.30.3 The trolley shall have swivel wheels or equivalent facilities for operation.

5.3.30.4 The trolley shall make the load rack remain stable when the trolley passes through a 3° slope during loading and unloading.

5.3.30.5 When the trolley is loaded with the maximum weight, it shall remain stable when a force not ex-

ceeding 250 N is applied from any horizontal direction.

5.3.30.6 The trolley shall have a parking brake device to keep the fully loaded trolley stable on a 3° slope.

5.3.30.7 The trolley shall be cleaned and disinfected easily during use intervals.

5.4 Operation

5.4.1 General requirements

5.4.1.1 An operating cycle shall comply with the specified functional requirements through an automatic controller. The operating cycle shall include pre-washing, washing, rinsing, disinfection, and drying operations.

5.4.1.2 During the pre-wash, wash, and rinse cycles, ensure that the cleaning objects are fully submerged below the liquid surface for complete soak cleaning.

5.4.1.3 During the entire operating cycle, the value changes in temperature, pressure, or detergent concentration shall comply with the limits specified by the manufacturers and suitable for the items being processed.

5.4.1.4 The critical process variables in moist heat disinfection include time and temperature.

5.4.1.5 The chamber used for placing the load shall be able to be disinfected under the control of the automatic controller. The chamber disinfection can be independent of the normal cycle, and it is not required for chamber used only for drying purpose to have a disinfection cycle.

5.4.1.6 During continuous processing, the load rack and load shall not be cross-contaminated by other loads being processed simultaneously.

5.4.1.7 In the rinse and drying steps, the quality of the medium in contact with the load shall at least comply with the manufacturer's specifications to avoid adverse effects on the processed items or impairing their intended use. The medium includes, but is not limited to, liquids and materials that come into direct contact with the load.

5.4.1.8 During the pre-washing, washing, rinsing, and disinfection cycles, the surface temperature of the load, inner wall, drain outlet, and load rack inside the working chamber shall comply with the following requirements.

a) The surface temperature measured shall have an error within ±5℃ of the design temperature.
b) The temperature difference between any two points shall not exceed 5℃.

5.4.2 Pre-washing

a) Use a combination method of vacuum-assisted boiling, vapor phase boiling, and pressure restoration to remove large contaminants on the surface of the instruments and soften blood and protein coagulants in preventing blood and protein from coagulating during operation.
b) The water temperature shall not exceed 45℃ to prevent protein coagulation. The pre-wash time shall be ≥2 minutes, and the vacuum be <−90 kPa.

5.4.3 Washing

a) Add chemical agents (detergents) and use a combination method of vacuum-assisted boiling, liquid phase boiling, vapor phase boiling, and pressure restoration to wash contaminants on the instruments.
b) Main parameters: The default washing time is 10 minutes, and the water temperature range is 45℃ ~90℃ . The washing temperature shall be set according to the detergent manufacturer's requirements as follows.
   i. Conventional detergent (e.g., multi-enzyme detergent) shall be used at 45℃~50℃, with a vacuum of <−80 kPa.
   ii. Strong alkaline detergent shall be used at 60℃~90℃, with a vacuum of <−20 kPa.
c) The washing timing shall start when the temperature measured by the temperature sensor of the washer-disinfector reaches the preset washing temperature.
d) Set corresponding programs for different types of instruments, which shall at least include programs for lumened instruments and solid instruments. All set programs shall be validated to ensure the effectiveness of

washing and disinfection.

5.4.4 Rinsing

a) Use a combination method of vacuum-assisted boiling, vapor phase boiling, and pressure restoration to remove residual detergents and contaminants.

b) The water quality shall comply with the requirements in Section 4.3.9. The water temperature range shall be 15℃~50℃, the rinsing time be ⩾2 minutes, and the vacuum be < −80 kPa. At least two rinsing cycles shall be able to set.

c) During the entire rinsing cycle, ensure that the rinsing objects are fully submerged below the liquid surface for complete soak rinsing.

d) Cleaning effectiveness:

i. Visual inspection and/or inspection with a light source magnifier shall be performed for daily monitoring of cleaning effectiveness. The surface of the instruments, including joints and teeth, shall be clean and free of blood stains, dirt, scale, and rust after rinsing. The inner surface of the lumen shall be free of visible contaminants. A sight glass finer than that of an endoscope lumen should be used to observe the inner surface of the lumen.

ii. For requirements of cleaning effectiveness and test methods, refer to Appendix B and WS 310.2.

5.4.5 Disinfection

5.4.5.1 Moist heat disinfection

a) The water quality shall comply with the requirements in Section 4.3.9. Use a combination method of vacuum-assisted liquid phase boiling disinfection, liquid phase boiling, and pressure restoration to disinfect.

b) For medical instruments, appliances, and items that are used directly after disinfection, the disinfection temperature shall be > 90℃, the time be >5 minutes, and the vacuum be <−20 kPa, or the A0 value be >3000. For items that undergo further sterilization after disinfection, the disinfection temperature shall be >90℃, the time be >1 minute, or the A0 value be >600. In high-altitude areas, the disinfection temperature can be reduced to 85℃, and the disinfection time shall be extended.

c) Disinfection effectiveness:

i. The A0 value on the surface of the load rack and the basket shall be no less than 600. Real-time monitoring and recording of the temperature, time, and A0 value shall be conducted during each disinfection cycle.

ii. The disinfection effectiveness shall comply with the requirements in the standard (file No. WS/T 10009). The disinfection effectiveness of complex instruments and lumened instruments shall comply with the requirements in the standard (file No. GB/T 38497).

5.4.5.2 Chemical disinfection

The parameters for chemical disinfection with disinfectants shall follow the requirements of disinfectant manufacturers.

5.4.6 Drying

a) Methods of hot air (impulse) drying, vacuum drying, or a combination of both are available for drying.

b) The temperature set shall not exceed 110℃.

c) The hot air or compressed air used for drying cannot reduce the cleanliness of the load or introduce microbial contamination into the load; clean air can be obtained by a high-efficiency particulate air (HEPA) filter.

d) No residual water shall be detected after the drying step.

5.5 Safety performance

5.5.1 Electrical safety shall comply with the requirements in the standards (files No. GB 4793.1 and GB 4793.4).

5.5.2 Electromagnetic compatibility shall comply with the requirements in the standard (file No. GB/T 18268.1).

6 Test methods

Refer to Appendix A.

Appendix A

（Normative）

Test methods

A. 1 Test conditions

The test conditions shall comply with the provisions in Section 4.3.

A. 2 General requirements

A.2.1 Refer to the drawings and technical documents of the washer-disinfector.

A.2.2 Materials

Inspect the design documents, usage documents, and physical samples of the materials.

A.2.3 Appearance

Inspect it visually and operationally.

A. 3 Structure

A.3.1 General requirements

Inspect and validate this item in practical operation.

A.3.2 Working chamber

A.3.2.1 Before the drying step begins, interrupt the washer-disinfector's program and visually inspect the chamber and the load rack. Then fill all liquid tanks and reservoirs with water to the highest water level required for normal operation and then drain them. Visually inspect the tanks, reservoirs, chamber, load rack, and ensure that no residual water is present.

A.3.2.2 Inspect it operationally.

A.3.2.3 Operational inspection. The chamber shall automatically relieve pressure when the pressure exceeds atmospheric pressure by +20 kPa. There shall be no leakage before the over-pressure protection device is triggered.

A.3.3 Door

A.3.3.1 Inspect the door's form and function.

A.3.3.2 Operate the washer-disinfector and inspect for fluid leakage at the door seal. Refer to the instructions for cleaning and replacing the door seal and validate the water residue when the door is opened.

A.3.3.3 Operate the washer-disinfector and validate the door opening condition.

A.3.3.4 Simulate a fault and inspect the fault display. Inspect the measures to prevent direct access to the load when the door is opened.

A.3.3.5 Validate the door unlocking operationally.

A.3.3.6 Inspect if a special device is provided to securely fix the door in the open position.

A.3.3.7 Simulate the situation in which the door is not properly locked and inspect if the operating cycle can be launched. Inspect if an override control is provided for maintenance purposes.

A.3.3.8 Simulate the situation in which the door drive mechanism fails and inspect if the door can be manually opened.

A.3.3.9 Simulate the situation in which an obstacle is present during the door closing and inspect if the door stops automatically and if an alarm is displayed.

A.3.3.10 Inspect it operationally.

A.3.3.11 Simulate a fault and inspect it operationally.

A.3.3.12 Inspect it operationally.

A.3.3.13 Inspect it operationally.

A.3.3.14 Inspect it operationally.

A.3.3.15 Refer to the instructions for manual door opening and locking methods. Inspect the relevant displays on the washer-disinfector.

A.3.3.16 Inspect it operationally.

A.3.3.17 Inspect it operationally.

A.3.3.18 Inspect it operationally.

A.3.4 Pipes, fittings, and valves

A.3.4.1 Visually inspect all pipes to determine if there is a slope so that any liquid inside flows toward the drain outlet. If necessary, determine if the slope is in the expected direction using a gradienter.

A.3.4.2 Inspect or calculate the actual maximum temperature and pressure of the valve during operation and compare them with the technical data provided by the manufacturers.

A.3.5 Water supply

Inspect it operationally.

A.3.6 Ventilation system

A.3.6.1 Close and seal the working chamber using the method specified by the manufacturer, then launch an operating cycle. Disable the automatic controller and allow steam to continuously enter the

chamber. Observe where the steam is discharged.

A.3.6.2 Inspect it operationally.

A.3.6.3 Disconnect the external pipe above the chamber at a height of 1 meter (if a pipe at a location cannot be disconnected, disconnect the pipe at the chamber and leave a one-meter pipe connected to the chamber). Fix a container with a capacity of at least 500 mL (with a drain outlet at the bottom connected to a hose; the hose shall have a switch valve and a flow control valve) approximately 1 meter above the chamber's air vent. When the switch valve is closed, fill the container with (200±20) mL of cold water, open the valve, and adjust the flow control valve so that the contents of the container can be discharged within (60±5) seconds.

Refill the container with (200±20) mL of cold water and connect the hose to the pipe so that the open end of the hose is 600 mm~800 mm above the top of the chamber.

Load the chamber with a full load of dry items according to the manufacturer's instructions, close the chamber door, and then open the switch valve. Record the time to empty the container.

One minute after the container is emptied, open the chamber door and remove the load and any removable load containers. Place all removed items on absorbent paper and inspect all load surfaces and the absorbent paper for water marks.

A.3.7 Drainage system

A.3.7.1 Inspect the structure of the drainage system.

A.3.7.2 Block the drain outlet to prevent water from draining from the working chamber. Close the door and launch an operating cycle. At the end of the operating cycle, attempt to open the door normally. If the door can be opened and the water level is below the door seal, close the door and launch another operating cycle. This may need to be repeated multiple times until the water level at the end of the cycle is above the door seal.

This test is not necessary if the washer-disinfector is designed to prevent the fluid inside the working chamber from reaching the height of the door.

A.3.8 Air filter

Inspect it operationally and inspect the documents provided by the manufacturers.

A.3.9 Port validation

Inspect it operationally and using general measuring tools.

A.3.10 Pre-installed hot water tank

A.3.10.1 Inspect it operationally.

A.3.10.2 Fill the water tank and liquid reservoir to the maximum water level during normal operation, drain the water, observe if there is any residual water, and inspect the cleaning process.

A.3.10.3 Inspect the removable filter operationally and validate it.

A.3.10.4 Inspect the heater operationally.

A.3.10.5 Run the program and inspect the water temperature display.

A.3.10.6 Run the program and detect the water temperature in the tank; or operate the procedure and inspect if the washer-disinfector automatically completes the tank disinfection before rinsing.

A.3.10.7 Sample the terminal rinse water from the tank, which shall comply with the requirements in Section 4.3.9.

A.3.11 Vacuum-assisted boiling system

Inspect it operationally and calculate. The vacuum pump shall be inspected against the manufacturer's documents and validated.

A.3.12 Liquid phase boiling system

Inspect it visually and operationally.

A.3.13 Vapor phase boiling system

Inspect it visually and operationally, and calculate.

A.3.14 Disinfection system

Inspect it operationally.

A.3.15 Self-cleaning and disinfection system

Inspect it operationally.

A.3.16 Drying system

Inspect and validate this item in practical operation.

A.3.17 Control system

Inspect and validate this item in practical operation.

A.3.18 Override control of automatic control

Inspect and validate this item in practical operation.

A.3.19 Dosing system

Inspect and validate this item in practical operation.

A.3.20 Load temperature protection

A.3.20.1 Inspect and validate this item in practical operation.

A.3.20.2 Inspect and validate this item in practical operation.

A.3.20.3 Run a program with no load. After the temperature reaches the preset, simulate a fault condition to cause the operating temperature to exceed the normal value. The load temperature protection device shall activate when the temperature exceeds the preset temperature by +5℃.

A.3.20.4 Run the washer-disinfector according to the instructions, disable the automatic controller, and allow steam to continuously enter the chamber. Measure the maximum pressure in the chamber when the protection device activates using a pressure gauge.

A.3.21 Process temperature control

A.3.21.1 Temperature measuring equipment

A.3.21.1.1 Temperature sensor

The temperature sensor shall be the Class A platinum resistance sensor as specified in GB/T 30121, or thermocouple with a Class 1 tolerance as specified in GB/T 16839.1. Other sensors that have been validated to be equivalent or better are also available. The performance of the temperature sensor shall not be affected by environmental conditions (e.g., pressure and hot detergent).

The output of the temperature sensor shall be validated as follows. Submerge the temperature sensor in a heat source set within the disinfection temperature range, with a temperature fluctuation of ±0.1℃. After calibration and adjustment, the indicated error of the temperature measurement equipment connected to the temperature sensor shall not exceed 0.5℃.

A.3.21.1.2 Temperature recorder

One or more temperature recorders shall be connected to the temperature sensor(s) to record the temperatures measured at the specified locations during the test.

The temperature recorder shall record the temperature values from at least 12 temperature sensors. There can be multiple channels, and they can be independent of each other. The data recording interval for each channel shall not exceed 2.5 seconds.

The range of a temperature recorder shall be at least 0℃ ~100℃ . At an ambient temperature of (20±3)℃ , the error of the temperature recorder shall not exceed ±0.25℃ within the range of 0℃~ 100℃.

The error caused by ambient temperature changes shall not exceed 0.04℃/℃.

The minimum marking interval for the analog temperature recorder shall not exceed 1℃, the chart speed be at least 15 mm/min, and the resolution be at least 0.5℃.

The increment for the digital temperature recorder shall be no more than 0.1℃.

A.3.21.2 Load temperature test

During the temperature test for moist heat disinfection, the washing step shall be tested to avoid preheating the load, or the temperature at the start of the disinfection step be reduced to or below the minimum temperature of the washing step.

Place the temperature sensors as follows.

a) Place sensors at the diagonal and geometric center positions of the load rack.
b) Place at least one sensor on the load on each layer of the load rack (if the load rack has more than one layer, three sensors as maximum).
c) Place one sensor on the load known to reach the disinfection temperature range the latest.
d) Place one sensor on the load known to reach the disinfection temperature range the fastest.
e) Place one sensor near the temperature sensor.
f) Place one sensor near the process recorder or indicator sensor (if provided) for each chamber.

These positions shall be supported by type test data. If the manufacturer cannot provide this data, preliminary tests shall be conducted to measure the temperature of the entire load.

The temperature sensors shall maintain good thermal contact with the load and be placed at the slowest heating position of the load or inside the load.

This test shall be conducted for all types of load racks. Conduct four consecutive tests, with the first test being conducted at least 1 hour after the last run ("cold start"), and the interval between the next three test cycles shall not exceed 15 minutes ("hot start").

A.3.21.3 Chamber wall temperature test

Place the temperature sensors as follows.

a) Place one sensor at each corner of the chamber.
b) Place one sensor at the center of each side panel.
c) Place one sensor at the center of the top of the chamber.
d) Place one sensor near the temperature sensor as a reference sensor to measure the chamber temperature.

If lower temperatures can be measured at other positions (e.g., when part of the outer surface of the chamber is not insulated), additional sensors shall be installed in subsequent cycles.

Measure the temperatures reached during four operating cycles, with the first test being conducted at least 1 hour after the last run ("cold start"), and the interval between the next three test cycles shall not exceed 15 minutes ("hot start").

Operate the washer-disinfector with items that constitute a reference load.

For the multi-chamber washer-disinfector, tests can be conducted continuously or simultaneously in each chamber. In the latter case, 12 sensors shall be provided in each chamber.

A.3.22 Instruments and controls

A.3.22.1 Inspect and validate this item in practical operation.

A.3.22.2 Visually inspect the readability of all indicators and instruments.

A.3.22.3 An observer with normal vision shall observe the indicator or instrument at an illumination of (300±100) lx, at distances of 0.25 m~0.30 m and 0.95 m~1.00 m, respectively.

A.3.22.4 Inspect and validate this item in practical operation.

A.3.22.5 Inspect and validate this item in practical operation.

A.3.22.6 Run the cleaning program, inspect and record the temperature difference, or inspect the displayed information at the end of the cycle.

A.3.22.7 Inspect and validate this item in practical operation.

A.3.22.8 Inspect and validate this item in practical operation.

A.3.23 Temperature indicating device

Inspect the relevant technical documents provided by the manufacturers and perform a physical inspection. If necessary, test the temperature sensor and temperature indicating device.

A.3.24 Pressure indicating device

Inspect the relevant technical documents provided by the manufacturers and perform a physical inspection. If necessary, test the pressure-indicating device.

A.3.25 Time indicating device

Perform a physical inspection. Then, set a time interval of 3 minutes or 10 minutes and measure it with a stopwatch.

A.3.26 Operating cycle indicating device

Inspect and validate this item in practical operation.

A.3.27 Recording device

Operate the washer-disinfector according to the manufacturer's instructions, inspect it operationally, and validate the technical parameters of the recording device.

A.3.28 Fault indication

Inspect and validate this item in practical operation.

A.3.29 Load rack and basket

Inspect and validate this item in practical operation.

A.3.30 Trolley

Inspect and validate this item in practical operation.

A. 4 Operation

A.4.1 General requirements

A.4.1.1 Run the program and inspect the status indi-

cation at each step.

A.4.1.2 Run and validate the program.

A.4.1.3 Run and validate the program.

A.4.1.4 Run the program, inspect or calculate critical process variables and their numerical changes.

A.4.1.5 Run the program and inspect the status of the disinfection cycle.

A.4.1.6 Operate the washer-disinfector and inspect whether the load rack and load are contaminated by other loads being processed simultaneously.

A.4.1.7 Operate the washer-disinfector and inspect the condition of the medium in contact with the load during the terminal rinse and drying steps.

A.4.1.8 Run and validate the program.

A.4.2 Pre-wash

Run and validate the program.

A.4.3 Washing

Run and validate the program.

A.4.4 Rinsing

A.4.4.1 Run the program, inspect, and validate the requirements in Sections 5.3.4 a), b), and c). Collect the terminal rinse discharge water as close as possible to the drain pipe or sampling port of the washer-disinfector.

A.4.4.2 Follow the requirements in Appendix B and the standard (file No. WS 310.2).

A.4.5 Disinfection

A.4.5.1 Moist heat disinfection

A.4.5.1.1 Test the temperature recorded by the temperature recorder and calculate the A0 value.

A.4.5.1.2 Run the disinfection program and perform tests according to the standards such as the *Technical Standard for Disinfection (2002 Edition)*, WS/T 10009, and GB/T 38497. The disinfection effect shall comply with the requirements in the standard (file No. WS/T 10009). The disinfection effect for complex instruments and lumened instruments shall comply with the requirements in the standard (file No. GB/T 38497).

A.4.5.2 Chemical disinfection

Select a commonly used disinfectant. Run the disinfection program according to the working parameters specified by the disinfectant manufacturer. The disinfection effect shall comply with the requirements in the standard (file No. WS/T 10009), and the disinfection effect for complex instruments and lumened instruments shall comply with the requirements in the standard (file No. GB/T 38497).

A.4.6 Drying

A.4.6.1 Run a normal operating cycle according to the type of load specified by the manufacturer by filling the washer-disinfector with a suitable load and performing a cold start (at least 1 hour after the last operation). Within 5 minutes after the operating cycle is completed, place a colored crepe paper (e.g., blue or green) on a flat surface, then transfer the processed load from the washer-disinfector to the crepe paper. During the transfer, observe whether water flows from the load and inspect the moisture level of the crepe paper. If there are water spots on the crepe paper, it shall be considered that there is residual water.

When the test load includes items with lumens, compressed dry air shall be used to blow through them, and the exhaust shall be directed at a mirror. If the mirror fogs up or visible water droplets are formed from the expelled moisture, it shall be considered that there is residual water.

A.4.6.2 Inspect the way hot air or compressed air enters the working chamber for drying and validate the quality certification documents of the HEPA filter.

A.4.7 Safety performance

A.4.7.1 Perform according to the methods specified in the standards (files No. GB 4793.1 and GB 4793.4).

A.4.7.2 Perform according to the methods specified in the standard (file No. GB/T 18268.1).

Appendix B

（Informative）

Examples of test methods for detecting and assessing residual protein

B. 1 Summary

Visual inspection is performed preliminary to inspect cleaning effectiveness. Quantitative analysis of residual protein shall only be applied to products

that have passed visual inspection. The selection of quantitative detection methods shall consider their detection range, accuracy, and specificity, and shall be suitable for the acceptance criteria and the products being tested. The modified ortho-phthalaldehyde (OPA) method[1-3] and the bicinchoninic acid (BCA) method[4-5] are the preferred methods for protein quantification after sampling. Since the OPA and BCA methods do not directly measure proteins, residual process chemicals or other substances may interfere with protein measurement. Therefore, it is necessary to test negative controls (i.e., medical devices that are processed and extracted in the same way as the tested devices but are not contaminated) to exclude interference.

Note: Other validated protein detection methods are also available.

B.1.1 Sample processing

Obtain samples for residual protein analysis by rinsing (or extracting) the product or a specified area of the product with a 1% sodium dodecyl sulfate (SDS) aqueous solution.

Priority shall be given to extracting areas of the product that come into contact with patient tissues and pose a risk of transfer during repeated use. This avoids results from non-critical areas of the product.

pH of the 1% SDS solution used for extraction shall be adjusted to 11 using pH test paper with a scale of at least 0.5 pH units or a pH meter calibrated with 0.1 N Sodium hydroxide solution. The effectiveness of the protein extraction method shall be validated by ensuring that all residues are dissolved, for example, by using protein stains such as Coomassie Brilliant Blue R-250, Amido Black, SYPRO Ruby, STAINS ALL (broad-spectrum stain), or Ponceau S.

Note[1]: The spectroscopic detection methods described cannot effectively detect insoluble proteins in the extract.

Use the minimum volume of 1% SDS solution for extraction to avoid any analytical errors caused by using large volumes and to have an appropriate detection limit to assess the actual situation of residual protein on the sample surface.

Large-volume extraction can significantly reduce overall sensitivity due to dilution effects. Therefore, the extraction volume shall be as small as possible while ensuring that all contaminated surfaces are continuously wetted or submerged, allowing the extraction solution to flow over the sampling surface.

However, a volume of extraction that is too small can reduce protein recovery. Therefore, it is necessary to adjust the rinse volume. Wetting the product is more important than reducing the extraction volume below a given limit. Additionally, repeated extractions at a small volume are more effective than a single extraction at a large volume. If staining shows insoluble proteins, the extraction efficiency can be improved by heating the SDS solution (e.g., to 40°C) and using ultrasound.

Note[2]: Data [6] indicate that SDS solution at a pH of 11 and high temperature can be used to dissolve high molecular weight fibrin residues from blood samples.

The spectroscopic detection method cannot be used to measure proteins in any turbid solution that has not been filtered or calibrated by a separate turbidity measurement. If turbidity is caused by an error in post-processing, the cause shall be identified and corrected. Turbid samples can be filtered through a 0.2 μm syringe filter to remove turbidity, but the filter membrane shall not adsorb proteins. Membrane filtration shall be validated along with all other steps of protein determination.

Extraction using SDS solution shall be performed for a defined period with intensive stirring (either manually or using a vortex mixer) or rinsing. For example, extraction using SDS can be performed by soaking for 30 minutes, with 30 seconds of intensive stirring or rinsing every 10 minutes. Other validated extraction methods are also available. The extraction method shall ensure appropriate extraction efficiency values. An example is extracting proteins from the product surface using 2-5 mL of SDS solution in a polypropylene bag.

A sealed, sturdy, and large polypropylene (PP) bag containing 2-5 mL of 1% SDS solution can be

used to extract residual contaminants from the entire product. Once the product is sealed in the bag with 1% SDS solution, extraction can be performed by flipping or shaking the bag and manipulating the product through the bag. Hinged products shall be manipulated through the bag to allow the SDS solution to contact the hidden surfaces of the hinges.

Note[3]: Polypropylene, other bag materials, and plastic tubes are usually processed with slip agents or release agents (e. g., Urea amide), which can be released from the plastic surface during intensive mixing of the product and cause turbidity in the extraction solution. It is good practice to test negative controls (i. e., products that are processed and extracted in the same way as the test product but are not contaminated) to identify any interference. Extraction of products with cavities or large and easily accessible cavities (e. g., trocar) using a suitable polypropylene bag is also feasible. By tilting back and forth, the SDS solution can flow directionally through these cavities. The bag shall be rotated according to the design so that all internal areas come into contact with the extraction solution.

Example 1: Partial extraction of proteins from hinged products using 2-3 mL of SDS solution

Some hinged products (e.g., Crile clamps) are used in standardized tests to evaluate the cleaning effectiveness of critical functional areas such as hinges. In extraction in SDS solution, the hinge requires intensive activity at the joint.

Example 2: Extraction from a shaft tube using 2~5 mL of SDS solution

When extracting products with long and narrow lumens, one end can be placed in a beaker and fixed upright with a lab stand clamp. Use a pipette or syringe to inject 2~5 mL of SDS solution to rinse the lumen of the product. Draw the SDS solution from the beaker. During extraction, rinse the lumen back and forth 5 times at intervals (e.g., every 5 minutes) using the same SDS solution.

A similar extraction process can be used for demountable minimally invasive surgical (MIS) products by separating the shaft from the insert with the functional end and placing the insert in a test tube segment long enough and with an internal diameter sufficient to accommodate the product. Clamp or seal one end, add SDS solution for extraction, then clamp or seal the other end and rotate the product to allow the SDS solution to flow back and forth.

Samples with internal channels that may come into contact with contaminants and cannot be visually inspected shall be rinsed with SDS solution for sample collection.

B.1.2 Calibration of protein detection methods

Accurate quantification of residual protein depends on the standard protein used for the preparation of the method. The standard protein used for calibration is bovine serum albumin (BSA, Fraction V). Prepare or purchase a stock solution of BSA at a concentration of 200 mg/mL. Dilute this stock solution in 1% SDS solution to prepare a concentration gradient of dilutions (e. g., 200 μg/mL, 100 μg/mL, 50 μg/mL, 25 μg/mL, 12.5 μg/mL, and 6.25 μg/mL) and retain in clean test tubes. The protein content of the product extract is determined by comparing the measured value of the extract with the standard curve calculated from the regression curve of the standard solution of known concentration. Standard samples and extract samples shall be analyzed in the same way.

B. 2 Evaluation of residual protein by modified OPA method

B.2.1 Principle of operation

The modified ortho-phthalaldehyde (OPA) method is a quantitative method for determining primary amino groups, which are present on the free α-amino and lysine (ε-) groups of polypeptide chains. In the presence of N,N-dimethyl-2-mercaptoethylammonium chloride and primary amino groups, the OPA method forms a stable fluorescent chromophore, 2-alkylthio-2-alkylisoindole, which can be detected at 340 nm using spectrophotometer. Primary amines are ubiquitous in nature and can be present in chemicals used during processing, so the determination of negative controls shall be included to exclude potential interfering substances.

Note: Similar or more precise methods can be used, such as a fluorometer[7].

B.2.2 Procedure

When preparing the OPA reagent, dissolve 40 mg of Ortho-phthalaldehyde in 1 mL of Methanol (mix until completely dissolved), then add 50 mL of 0.1 M Sodium tetraborate buffer (pH of 9.3), 100 mg of N,N-dimethyl-2-mercaptoethylammonium chloride, and 1.25 mL of 20% SDS aqueous solution. Retain the solution in an opaque bottle to avoid light exposure and use it on the day of preparation.

Prepare a spectrophotometer blank solution by diluting the OPA reagent with 1% SDS solution in the same proportion for protein determination of the standard solution and product extract. Use the blank test value to zero the spectrophotometer. Adjust the spectrophotometer wavelength to 340 nm and use a quartz cuvette with a 1 cm light path (or a disposable semi-micro cuvette suitable for this wavelength).

When measuring the standard solution and product extract sample, use the same proportion of sample and OPA reagent. For example, add 200 µL of standard solution or extract sample to 1 mL (1∶5) of OPA solution freshly prepared. The ratio of sample to OPA reagent can be reduced to 1:1 as long as the pH of the mixture remains at 9.3 (confirmed using pH test paper). Lower dilution concentrations may cause the pH of the OPA reagent to change and potentially invalidate the results. Mix the reaction solution with a pipette or cover the cuvette with a cap and gently shake to mix the solution completely. After reacting for 5 minutes and removing all bubbles generated after mixing, measure the absorbance.

When the absorbance is >0.010, the sample analyzed may contain substances that absorb light at 340 nm. Therefore, the self-absorbance shall be determined and subtracted from the OPA results. The self-absorbance is determined by adding the sample at same proportion to 1% SDS solution (instead of OPA reagent). Pipette 200 µL of 1% SDS extract into 1 mL of 1% SDS solution, mix, and measure the absorbance of the 1% SDS solution. Subtract this from the absorbance of the sample after the OPA reaction and the protein mass determined relative to the calibrated BSA dilution (see B.1.2).

B.2.3 Calculation of protein content

Consider the volume of SDS solution used for extraction to calculate the total residual protein on the product or extracted part. Multiply the protein concentration (µg/mL) in the extract sample by the total volume (mL) of 1% SDS used to extract the tested product or area.

For example, if the measured protein concentration is 10 µg/mL and the extraction volume is 5 mL, the total residual protein is 50 µg. As mentioned above, unnecessarily high extraction volumes can lead to multiplied protein results, analytical interference, and interference with protein determination methods.

B.2.4 Acceptance criteria and result interpretation

Refer to the relevant literature on interfering substances.

B. 3 Evaluation of residual protein by BCA method

B.3.1 Principle of operation

The BCA method is similar to the biuret reaction. In an alkaline environment, proteins reduce Cu^{2+} to Cu^{+}, which combines with two molecules of BCA to form a purple chromophore with maximum absorption at 562 nm.

In the test environment, other substances that can reduce Cu^{2+} to Cu^{+} will also form the BCA chromophore. Therefore, performing a negative control group helps to exclude interference.

Note[1]: Test kits can be obtained commercially.

Note[2]: See cited works by Smith et al [4] and Stoschek[5].

B.3.2 Materials/Reagents

Prepare reagents A and B as follows.

Reagent A: Add 1 g of 2,2'-biquinoline-4,4'-dicarboxylic acid disodium salt, 2 g of Sodium carbonate, 0.16 g of Sodium tartrate, 0.4 g of Sodium hydroxide, and 0.95 g of Sodium bicarbonate to 100 mL of distilled water and adjust the pH to 11.25 with 10 M of Sodium hydroxide solution.

Reagent B: Add 0.4 g of copper sulfate pentahydrate to 10 mL of distilled water.

Prepare the standard solution (SWS) by mixing 100 parts of reagent A with 2 parts of reagent B. Retain the SWS solution in a light-proof bottle to avoid light exposure and use it on the day of preparation.

B.3.3 Procedure

Add 100 µl of extract or standard solution to 1 mL of SWS (or 200 µl of extract or standard solution and 2 mL of SWS) as an experimental group; add 100 µl of purified water to 1 mL of SWS as a blank control group. Mix them and react at room temperature for two hours (20℃±1℃). Then measure the blank control, standard BSA solution, and product extract sample using a spectrophotometer at 562 nm for 10 minutes. Reset to zero by measuring the purified water in a clean test tube. Adjust the value by subtracting the blank value from the measured value.

Note: The color development of the BCA test is based on the rate of reaction (there is no true reaction endpoint); the color of the reaction becomes darker as the reactants (Cu^{2+} and excess BCA) are consumed. There is no significant deviation of the color-growing mass within 10 minutes.

The protein concentration of the product extract is determined by comparison with a BSA standard (see Section B.1.2).

The protein concentration of the product extract is equivalent to a BSA standard.

B.3.4 Calculation of total protein

The total protein of the extract is calculated (see B.2.3).

B.3.5 Acceptance criteria and result interpretation

Refer to the relevant literature on interfering substances.

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