DOI: 10.11910/j.issn.2791-2043.2026.1.01

ICS 11.080
CCS C 59

NATIONAL STANDARD

GB 30689—2026

Replaces GB 30689—2014

Hygienic requirements for automated washer-disinfector for endoscope

Issued on January 28, 2026 Implemented on February 01, 2027

Issued by **State Administration for Market Regulation** and
National Standardization Administration

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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).

This document replaces the *Hygienic requirements for washer-disinfectors employing chemical disinfection for thermolabile endoscopes* (GB 30689—2014). Compared with the standard GB 30689—2014, apart from structural adjustments and editorial changes, the main technical changes are as follows:

- Changes the scope (see Section 1 of this edition and Section 1 of the 2014 edition);
- Changes the terms and definitions (see Section 3 of this edition and Section 3 of the 2014 edition);
- Removes “Name and Model” (see Section 4 of the 2014 edition);
- Changes the performance requirements and adds general requirements (see Section 4.1 of this edition and Section 5 of the 2014 edition);
- Changes the requirements for leakage test, cleaning, disinfection temperature and final rinse (see Sections 4.2, 4.3, 4.4.2, 4.5 of this edition and Sections 5.1, 5.2, 5.3.1, 5.3.2, 5.4 of the 2014 edition);
- Changes the control requirements (see Section 5.1.4 of this edition and Sections 6.3, 6.4 of the 2014 edition);
- Adds requirements for recording and traceability systems (see Section 5.4);
- Adds hygienic indicators and test methods (see Section 6);
- Removes electrical safety requirements (see Section 7 of the 2014 edition);
- Adds requirements for nameplate and instruction manual (see Sections 8.1 and 8.2).

Attention is drawn to the possibility that some elements of this document may be the subject of patent rights. The issuing authority shall not be held responsible for identifying any or all such patent rights.

This document is proposed and managed by the National Disease Control and Prevention Administration.

The previous editions of this document and the editions it replaces are as follows:

- First issued as GB 30689—2014 in 2014;
- This is the first revision.

Hygienic Requirements for Automated Washer-disinfector for Endoscope

State Administration for Market Regulation, National Standardization Administration

1 Scope of Application

This document specifies the performance requirements, control requirements, hygienic indicators, transport, storage and packaging, labeling, nameplate and instruction manual for automated washer-disinfectors for endoscopes, and describes the test methods for hygienic indicators.

This document applies to automated washer-disinfectors for flexible endoscopes.

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.

Graphical symbols marking for handling and storage of packages (GB/T 191)

Standards for drinking water quality (GB 5749)

Hygienic requirements for disposable sanitary products (GB 15979—2024)

Hygienic requirements for ozone disinfector (GB 28232)

Hygienic requirements for acidic electrolyzed water generator (GB 28234)

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

General requirement for label and instruction book of disinfection products (GB 38598)

Test methods of disinfection products (WS/T 10009)

Pharmacopoeia of the People's Republic of China

3 Terms and definitions

The terms and definitions defined as follows apply to this document.

3.1 Automated washer-disinfector for endoscope

Automated equipment for cleaning and disinfecting flexible endoscopes.

Note: Abbreviated as endoscope washer-disinfector.

3.2 Leakage test

A test to confirm the integrity of the endoscope's outer covering and channels.

3.3 Self-disinfection cycle

A disinfection treatment carried out by the endoscope washer-disinfector on itself when empty, covering all liquid circulation systems, chambers, tanks, and other components that come into contact with water or solutions used for cleaning, disinfection, and rinsing of instruments.

3.4 Medical detergent

A preparation used to enhance the cleaning effect of water on soils and contaminants on medical devices, instruments, and other related items.

4 Performance Requirements

4.1 General requirements

4.1.1 The endoscope washer-disinfector shall have the functions of cleaning, disinfection, final rinse, self-disinfection and traceability.

4.1.2 When equipped with an automatic leakage test function, if a leakage of the endoscope is detected, there shall be a visible or audible alarm signal, and the running program shall be automatically interrupted or its operation shall be stopped. When equipped with an interactive leakage test function, bubbles shall be seen emerging from the leak.

4.1.3 When equipped with a drying function, after drying the inner surfaces of the endoscope shall show no visible water residue.

4.1.4 For endoscope washer-disinfectors using on-site generated disinfectant, a disinfectant sampling port or sampling test function shall be provided. For endoscope washer-disinfectors equipped with final rinse water purification and disin-

fection functions, a final rinse water sampling port shall be provided.

4.1.5 Endoscope washer-disinfectors shall have a door type of the double-door, single-door, flip-top door or drawer door.

4.2 Leakage test

When the endoscope washer-disinfector has an automatic leakage test function, it shall ensure that the endoscope is not damaged by liquid entering during the operating cycle. The parameters of the endoscope washer-disinfector leakage test (e.g. pressure, duration, maximum allowable leakage) shall be consistent with the parameters indicated in the instruction manual. The test procedure shall ensure that one leakage test is completed before the endoscope comes into contact with the liquid inside the endoscope washer-disinfector.

4.3 Cleaning

4.3.1 Rinse (flush)

The endoscope washer-disinfector shall be capable of rinsing the internal and external surfaces of the endoscope. The rinse water shall not be reused and shall be discharged after each stage.

4.3.2 Detergent wash

The manufacturer of the endoscope washer-disinfector shall recommend a compatible medical detergent. The water containing the medical detergent shall not be reused and shall be discharged after each stage.

4.3.3 Rinse

It shall ensure that residual detergent does not affect the disinfection efficacy. The quality of the rinsing water shall comply with the manufacturer's specifications for the endoscope washer-disinfector and with the standard GB 5749. The rinsing water shall not be reused and shall be discharged after each stage.

4.4 Disinfection

4.4.1 The manufacturer of the endoscope washer-disinfector shall recommend a compatible disinfectant. The disinfectant used shall comply with relevant hygienic standards.

4.4.2 The disinfection temperature shall be within the temperature tolerance range of the endoscope and shall satisfy the disinfectant manufacturer's specifications.

4.4.3 The disinfection phase shall be timed and the time shall be displayed on a screen.

4.5 Final rinse

For the final rinse, final rinse water meeting Section 6.1.3.1 Hygienic indicators shall be used. The final rinse water shall be treated using a disinfection treatment device. For sterilized endoscopes, the final rinse water shall be simultaneously treated by filtration through a filter membrane of 0.2 μm or less and by a halogenated resin filter cartridge. The residual disinfectant level after rinsing shall comply with relevant national standards or the instruction manual requirements. The final rinse water shall not be reused and shall be discharged after each stage.

4.6 Drying

When an endoscope drying program is provided, residual rinse water in the instrument channels may be expelled by filtered air. After drying, the internal surfaces of the instrument shall show no visible water residue. If an alcohol drying program is provided, it shall ensure no damage to the endoscope.

4.7 Self-disinfection

4.7.1 A self-disinfection program shall be provided to ensure that the endoscope washer-disinfector does not cause cross-contamination between endoscopes.

4.7.2 The manufacturer shall provide information on the parts that can be treated by the self-disinfection program and indicate whether water treatment equipment is included.

4.7.3 The self-disinfection program of the endoscope washer-disinfector shall meet the following conditions

a) It can be operated under an automatic control program;

b) It can be selected by the user;

c) It can disinfect the entire liquid circuit system;

d) It warns that the self-disinfection program is to be run in empty mode;

e) The self-disinfection program uses thermal disinfection or chemical disinfection for self-disinfection. For thermal disinfection, the

A_0 value shall be at least 600; for chemical disinfection, it shall meet the qualification requirements for surface disinfection.

5 Control Requirements

5.1 Cleaning and disinfection system

5.1.1 During cleaning, disinfection and rinsing, it shall ensure that the various liquids come into contact with the channels and cavities that need to be processed.

5.1.2 The manufacturer shall specify the maximum and minimum flow rate and the maximum pressure for each channel or channel system. When processing the endoscope, the pressure and flow rate specified by the endoscope manufacturer shall not be exceeded.

5.1.3 During endoscope cleaning, disinfection and rinsing, if an endoscope channel is not properly connected to the endoscope washer-disinfector resulting in leakage, there shall be an alarm indication.

5.1.4 There shall be a monitoring and control program to ensure that the disinfectant concentration, disinfection temperature and disinfection time are consistent with the settings, and the following requirements shall be met.

a) Reusable disinfectant shall be monitored for concentration, such as using a built-in device or concentration test strips. When diluting for use, the dilution factor shall be calculated from the initial concentration and the in-use concentration of the disinfectant.

b) The manufacturer shall specify the temperature range for each stage. It shall be ensured that the temperature of each stage is controlled above the specified temperature and within +5℃ . An alarm shall be triggered when the temperature is outside the specified range.

c) Each chemical liquid shall be contained in a separate container. A control method shall be provided to ensure that the preset dose is consistent with the actual dose used. The error of the chemical liquid dose shall be less than ±5% of the set value. When the dosing system fails, an alarm shall be triggered.

d) Under all circumstances, the automatic controller shall verify that the exposure time for each liquid meets the setting. The exposure time for each stage shall be verified.

5.1.5 The manufacturer shall ensure that the liquid flowing into each channel meets the requirements for cleaning, disinfection and rinsing.

5.2 Ventilation and drainage system

The design and production of the endoscope washer-disinfector shall ensure the safe discharge of waste gas and waste liquid.

5.3 Mechanical requirements

5.3.1 The chambers and channels shall be made of 304 stainless steel or other anti-corrosion materials stable to the disinfectant.

5.3.2 The endoscope washer-disinfector shall have good sealing performance. Under normal working conditions, there shall be no water leakage or air leakage.

5.4 Recording and traceability system

The main parameters of cleaning, disinfection, rinsing, self-disinfection and other processes shall be recorded, displayed and stored. Electronic data shall be storable for more than 3 months, achieving traceability.

6 Hygienic Indicators and Test Methods

6.1 Water

6.1.1 Cleaning water

Water quality shall comply with the standard GB 5749.

6.1.2 Rinsing water

Water quality shall comply with the standard GB 5749.

6.1.3 Final rinse water

6.1.3.1 Hygienic indicators

6.1.3.1.1 Conductivity: Before disinfection, the conductivity shall be ⩽15 μS/cm (25℃).

6.1.3.1.2 Microorganisms: The total bacterial count shall be ⩽10 CFU/100 mL, and it shall be ensured that the final rinse water is not contaminated by pathogenic microorgan-

isms. *Pseudomonas aeruginosa* and *mycobacteria* shall not be detected in 100 mL of final rinse water.

6.1.3.1.3 For final rinse water used for endoscope sterilization, the sterility test shall be performed and the result shall be negative.

6.1.3.2 Test methods

6.1.3.2.1 Conductivity: Test using a conductivity meter.

6.1.3.2.2 Microorganisms: The total bacterial count determination shall be carried out under strict aseptic conditions. Take a 100 mL sample of final rinse water, filter it using a 0.45 μm membrane filter, then place the filter membrane on the surface of the culture medium. The test method shall comply with the standard WS/T 10009. The test method for Pseudomonas aeruginosa shall comply with the standard GB 15979—2024, Appendix B. The test method for mycobacteria shall comply with the standard WS/T 10009. For testing other pathogenic microorganisms, testing shall be carried out according to relevant standards and specifications.

6.1.3.2.3 For final rinse water used for endoscope sterilization, sample from the rinse water sampling port and test according to the sterility test method specified in the *Pharmacopoeia of the People's Republic of China*.

6.2 Drying air

The air used to dry residual rinse water inside the endoscope channels shall be filtered first. An high-efficiency filter shall be used for the air filter and shall be replaced regularly.

6.3 Detergent

Medical detergents shall be safe, effective and capable of removing the corresponding soiling.

6.4 Disinfectant

6.4.1 The disinfectant used in the endoscope washer-disinfector shall meet the requirements of Appendix A and shall be tested in conjunction with the endoscope washer-disinfector.

6.4.2 Disinfectants used in endoscope washer-disinfectors for endoscope sterilization shall comply with the standard WS/T 10009.

6.4.3 Reusable disinfectants for endoscope washer-disinfectors shall be subjected to a continuous use simulation test, and the disinfection efficacy shall meet the requirements of the standard GB/T 38497.

6.5 Endoscope washer-disinfector

6.5.1 After cleaning, the surfaces of the endoscope, including the internal surfaces of the channels, shall show no visible soiling. For surfaces with channel internal diameters ≥2 mm, a borescope finer than the endoscope channel shall be used for observation.

6.5.2 The endoscope washer-disinfector shall be subjected to a simulated field test for disinfection efficacy, which shall meet the requirements of the standard GB/T 38497. If sterilization capability is claimed, a simulated field test for sterilization efficacy shall be carried out according to the standard WS/T 10009.

7 Transport, Storage and Packaging

7.1 Transport

During transport, measures shall be taken to protect from sunlight and rain; handling shall avoid inversion; or storage and transport shall be carried out according to the manufacturer's specified storage conditions.

7.2 Storage

Products shall be stored in a cool, dry place, in a well-ventilated and clean indoor environment, or according to the manufacturer's specified storage conditions.

7.3 Packaging

7.3.1 Each endoscope washer-disinfector shall be covered with neutral plastic film and fixed inside the packaging box to prevent movement during transport.

7.3.2 Each packaging box of the endoscope washer-disinfector shall have an instruction manual

and a certificate of conformity.

7.3.3 The outer packaging shall be a wooden box or as specified in the purchase contract.

8 Labeling, Nameplate and Instruction Manual

8.1 Labeling and nameplate

8.1.1 The nameplate of each endoscope washer-disinfector shall contain at least the following information

a) Manufacturer's name, trademark and address;
b) Product name and model;
c) Supply voltage, frequency, input power;
d) Date of manufacture and product number;
e) Total weight of product (kg).

8.1.2 The certificate of conformity shall contain at least the following information

a) Manufacturer's name;
b) Product name and model;
c) Inspection date;
d) Inspector's code.

8.1.3 The outer packaging box shall contain at least the following information

a) Manufacturer's name and address;
b) Product name and model;
c) Date of manufacture and product number;
d) Dimensions (length × width × height);
e) Gross weight (kg);
f) Storage and transport pictorial markings shall comply with the standard GB/T 191.

8.2 Instruction manual

The instruction manual shall comply with the standard GB 38598. For the disinfectant recommended by the manufacturer of the endoscope washer-disinfector, the following requirements shall be stated in the instructions for use.

a) For single-use disinfectants, the concentration shall be monitored for each batch before use.
b) For reusable disinfectants, the concentration shall be measured once after preparation. The monitoring frequency shall follow the product instruction manual. If the instruction manual does not specify, when the number of endoscopes disinfected reaches half of the specified number, the concentration shall be monitored before disinfecting each endoscope.
c) For on-site generated disinfectants, the concentration shall be measured at each use by sampling at the disinfectant sampling port of the endoscope washer-disinfector.
d) Single-use disinfectants shall be discharged after each disinfection cycle. Reusable disinfectants shall be used within the limited number of cycles, time, and effective concentration and then discharged.

Appendix A

(Normative)

Laboratory Evaluation Method for Disinfection Efficacy

A. 1 Purpose

To test the disinfection efficacy of disinfectants used in endoscope washer-disinfectors in a laboratory setting.

A. 2 Reagents and culture media

A.2.1 Test strains

Escherichia coli (8099 or NCTC 10538), *Staphylococcus aureus* (ATCC 6538), *Pseudomonas aeruginosa* (ATCC 15442), *Candida albicans* (ATCC 10231), *Mycobacterium abscessus* subsp. *abscessus* [ATCC 19977 or CMCC(B) 93326], Poliovirus type I (PV-I) vaccine strain, and *Bacillus subtilis* var. *niger* spores (ATCC 9372). Other strains may be added depending on the specific use of the disinfectant or special test requirements.

A.2.2 Reagents

0.3% bovine serum albumin, neutralizer, tryptic soy broth (TSB).

A.2.3 Culture media

Tryptic soy agar (TSA).

A. 3 Test methods

A.3.1 The neutralizer identification test shall be carried out according to the standard WS/T 10009.

A.3.2 The quantitative suspension test shall be car-

ried out according to the standard WS/T 10009.

A.3.3 The virus inactivation test shall be carried out according to the standard WS/T 10009.

A.3.4 If sporicidal activity is not claimed, the *Bacillus subtilis* var. *niger* spore test may be omitted. If the *Bacillus subtilis* var. *niger* spore test has been performed, other microorganism tests may be omitted unless specifically required.

A.3.5 For acidic electrolyzed oxidizing water and ozone used for endoscope disinfection, their test methods shall follow the standards GB 28234 and GB 28232.

A.3.6 Either the suspension method or the carrier method may be adopted for testing.

A.4 Evaluation of results

Under the shortest exposure time, lowest in-use concentration, and lowest temperature specified in the disinfectant's instruction manual for the endoscope washer-disinfector, the laboratory test results for the disinfectant shall all meet the requirements of Table A.1, achieving disinfection qualification.

Table A.1 Microorganism killing indicators in laboratory tests

Indicator strain	Log kill value	
	Suspension method	Carrier method
Escherichia coli (8099 or NCTC 10538)	≥5.00	≥3.00
Staphylococcus aureus (ATCC6538)	≥5.00	≥3.00
Pseudomonas aeruginosa (ATCC 15442)	≥5.00	≥3.00
Candida albicans (ATCC 10231)	≥4.00	≥3.00
Mycobacterium abscessus subsp. *abscessus* [ATCC 19977 or CMCC(B)93326]	≥4.00	≥3.00
Poliovirus type I (PV-I) vaccine strain	≥4.00	≥3.00
Bacillus subtilis var. *niger* spores (ATCC 9372)	≥5.00	≥3.00