TECHNICAL SPECIFICATION

ISO/TS 15883-5

First edition
2005-11-15

Washer-disinfectors —

Part 5: Test soils and methods for demonstrating cleaning efficacy

Laveurs désinfecteurs —
Partie 5: Terrains d'essai et méthodes pour démontrer l'efficacité de nettoyage

Reference number
ISO/TS 15883-5:2005(E)

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Published in Switzerland

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;

— an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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

ISO/TS 15883-5 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

ISO 15883 consists of the following parts, under the general title *Washer-disinfectors*:

— *Part 1: General requirements, terms and definitions and tests*

— *Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.*

— *Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers*

— *Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes*

— *Part 5: Test soils and methods for demonstrating cleaning efficacy* [Technical Specification]

Introduction

Verification of cleaning efficacy is a key aspect of establishing satisfactory performance of a washer-disinfector. The current state of knowledge has not permitted development of a single internationally acceptable test method. As an interim measure, the Technical Committees responsible for the ISO 15883 series of standards on washer-disinfectors (ISO/TC 198 and CEN/TC 102) have decided that the cleaning efficacy of washer-disinfectors claiming compliance with the ISO 15883 series of standards be demonstrated by referring to the test soils and methods that are currently used in a number of different countries. For the convenience of the user of the ISO 15883 series of standards, these test soils and methods are described in this Technical Specification. It should be noted that it remains the intention of the Technical Committees to develop a single test method.

Washer-disinfectors —

Part 5:
Test soils and methods for demonstrating cleaning efficacy

1 Scope

This Technical Specification includes the test soils and methods that can be used to demonstrate the cleaning efficacy of washer-disinfectors (WD) according to the ISO 15883 series of standards.

The inclusion of the test soils and methods in this Technical Specification does not indicate that they are of equivalent sensitivity in their determination of cleaning efficacy.

Acceptance criteria are included, based on visual inspection and/or a microbiological end-point as stated for each method. Where chemical detection of residual soiling is required/sought, methods can be complemented by the specific determination of a residual component of the applied test soil.

NOTE 1 The test soils and methods included in this Technical Specification are sourced from national standards and published documents submitted by member bodies of the Technical Committee preparing this Technical Specification. They have been edited only to provide a uniform format within this Technical Specification.

NOTE 2 An example of this is the use of the peroxidase test (see Annex J) to detect residual blood (haemoglobin) from the test soil applied to surgical instruments or flexible endoscopes (e.g. using the method described in Annex G). See also ISO 15883-1:2005, Annex D.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3166-1, *Codes for the representation of names of countries and their subdivisions — Part 1: Country codes*

ISO 15883-1:2005, *Washer-disinfectors — Part 1: General requirements, terms and definitions and tests*

3 Applicability

3.1 Where any of the test methods specified below deviate from the test method for cleaning efficacy specified in ISO 15883-1, the method given in ISO 15883-1 shall be used (see ISO 15883-1:2005, 6.10). Cleaning efficacy, for example, shall be determined after exposure to only the cleaning part of the operating cycle.

3.2 Table 1 includes a summary of the test soils which are included in this Technical Specification. The test soils are listed for the specific type of WD loads for which they were specified; the same test soils may be used also for other types of loads: for example, soils specified for surgical instrument may be used for other metal components.

Table 1 — Summary of test soils including their allocation to the type of load

Load type	Country code[a]	Reference in Bibliography	Constituents of soil	Annex in this Technical Specification
Surgical instruments (including rigid endoscopes)	AT	[34]	Heparinzed sheep blood coagulated with protamine	Annex A
	DE	[32], [33]	Sheep blood, *E. faecium*[b] Egg yolk, *E. faecium*[b] Semolina, butter, sugar, milk powder, *E. faecium*[b]	Annex G
	DE	[41], [42], [43]	Tetramethylbenzidine, hydrogen peroxide solution, bovine haemoglobin	Annex J
	NL	[39]	Bovine serum albumin fraction 5, porcine gastric mucin type 3, bovine fibrinogen fraction 1, bovine thrombin	Annex K
	SE	[24]	Citrated cattle blood coagulated with calcium chloride	Annex M
	UK	[28], [30]	Defibrinated horse/sheep blood, egg yolk, dehydrated hog mucin	Annex N
	US	[31] [47]	Protein/organic soil (user preference), *B. atrophaeus* endospores Albumin, haemoglobin, fibrinogen, thrombin	Annex S
Bowls, dishes, receivers	SE	[24]	Citrated cattle blood coagulated with calcium chloride	Annex M
	UK	[28], [30]	Defibrinated horse/sheep blood, egg yolk, dehydrated hog mucin	Annex N
Anaesthesia equipment / accessories	AT	[36]	Nigrosin, wheat flour, hens egg	Annex B
	DE	[32], [33]	Sheep blood, *E. faecium*[b]	Annex G
	SE	[24]	Citrated cattle blood coagulated with calcium chloride	Annex M
	UK	[28], [30]	Glycerol, dehydrated hog mucin, horse serum, unbleached plain flour, aqueous safranine solution, water	Annex O
Infant feeding bottles	DE	[32], [33]	Sheep blood, *E. faecium*[b] egg yolk, *E. faecium*[b] semolina, butter, sugar, milk powder, *E. faecium*[b]	Annex G
Baby bottles and suction bottles	SE	[24]	Citrated cattle blood coagulated with calcium chloride	Annex M

Table 1 (*continued*)

Load type	Country code[a]	Reference in Bibliography	Constituents of soil	Annex in this Technical Specification
Bedpans	AT	[36]	Nigrosin, wheat flour, hens egg, instant potato flakes,	Annex C
	DE	[22], [23], [38]	Bovine albumin, mucin, maize starch *E. faecium*[b]	Annex H
	SE	[24]	Citrated cattle blood coagulated with calcium chloride	Annex M
	UK	[27], [30]	Unbleached plain flour, water soluble adhesive wallpaper paste, hens egg, black Indian ink, water	Annex P
Urine bottles	AT	[36]	Nigrosin, wheat flour, hens egg	Annex D
	SE	[24]	Citrated cattle blood coagulated with calcium chloride	Annex M
	UK	[27], [30]	Defibrinated horse/sheep blood, water soluble adhesive wallpaper paste, hens egg, black Indian ink, water	Annex Q
Flexible endoscopes	AT	[34], [44]	Nigrosin, wheat flour, hens egg, *E. faecium*[b]	Annex E
	DE	[34], [35]	Blood, *E. faecium*[b]	Annex I
	DE	[41], [42], [43]	Tetramethylbenzidine, hydrogen peroxide solution, bovine haemoglobin	Annex J
	FR	[37]	Biofilm formed by *Pseudomonas aeruginosa*	Annex F
	NL	[40]	Bovine serum albumin, procine mucin, bovine thrombin, bovine fibrinogen	Annex L
	UK	[30]	Glycerol, dehydrated hog mucin, horse serum, unbleached plain flour, aqueous safranine solution, water	Annex R
	US	[31] [47]	Protein/organic soil (user preference), *B. atrophaeus* endospores Bacteria, protein, carbohydrate, endotoxin, haemoglobin	Annex S
Stainless steel items (including bedpans, urine bottles)	NL	[39]	Bovine albumin fraction 5, porcine gastric mucin type 3, bovine fibrinogen fraction 1, bovine thrombin	Annex K
Wash bowls	SE	[24]	Calcium stearate generated *in situ* from soap and calcium chloride solution	Annex M
Reusable medical instruments including flexible endoscopes	US	[31]	Protein/organic soil (user preference), *B. atrophaeus* endospores	Annex S

[a] Country code as specified in ISO 3166-1.

[b] The test soils and methods may also be used for microbial testing of disinfection efficacy of WDs according to the ISO 15883 series when requested by the user.

Annex A
(normative)

Test soil and method for surgical instruments (Austria)

A.1 Reference

The test methods using a heparinized blood test soil for testing and evaluating the cleaning efficacy of automated WDs for surgical instruments as an optional type test and operational test are based on Reference [34] and were adapted or complemented for the presentation in this Technical Specification.

A.2 Materials

— **Blood from a laboratory sheep**.

— **Heparin**[1)].

— **Protamine sulphate** or **hydrochloride**[1)].

Optional:

— **Cleaning-indicators for ordinary surgical instruments**[1)].

— **Cleaning-indicators for instruments for minimally invasive surgery**[1)].

A.3 Apparatus

— **Normal laboratory equipment**.

— **Paintbrush**, 25 mm in width and 4 mm of thickness.

— **Syringes,** of 20 ml capacity.

A.4 Preparation of test soil

A.4.1 Heparinized sheep blood

Add 0,1 ml heparin per 100 ml of sheep blood immediately after the blood is drawn (heparinized sheep blood).

A.4.2 Completion of the test soil

Directly before use bring the blood to room temperature.

Pour the heparinized blood into a clean and dry bowl, add 0,15 ml of protamine sulphate to each 10 ml of blood and mix well. The blood should coagulate within approximately 10 min to 20 min.

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1) Guidance on suitable commercially available products may be obtained from Austrian Standards Institute, Heinestr. 38, 1020 Vienna, Austria.

A.5 Storage

Store the blood and the protamine sulphate (or hydrochloride) in a refrigerator at 4 °C to 8 °C and according to the manufacturer's instructions respectively.

A.6 Test pieces

A.6.1 Ordinary surgical instruments

Surgical instruments with joints (scissors with joints and clamps with box locks at a ratio of 1:1) in sufficient numbers to provide a full load of the WD under test when using 20 test pieces per tray.

A.6.2 Instruments for minimally invasive surgery

As a surrogate for rigid endoscopes, dummies made of stainless steel tubing should be used with a wall thickness of approximately 1 mm and either:

— a length of 150 mm, inner diameter of 8 mm; or

— a length of 300 mm, inner diameter of 4 mm and 6 mm.

A.7 Inoculation of test pieces

A.7.1 Ordinary surgical instruments

Allow the blood to equilibrate to room temperature before use. Clean and dry the test instruments thoroughly. Apply the test soil to joints and corrugate surfaces of the instruments at ambient temperature using a paintbrush. Take care that the blood is used within approximately 10 min (in any case before complete coagulation). The total amount of the test soil should be about 0,05 % of the amount of water for the cleaning phase in the tank of the WD (e.g. 20 l water; 10 ml blood).

Place 20 pieces of the soiled instruments horizontally and at random on each of the trays.

All instruments shall be prepared and arranged on the tray within 30 min.

Leave the instruments on the tray to dry at ambient temperature and humidity for approximately 30 min. Then take each of the instruments and check them for excessive test soil (e.g. coagulated test soil spots ⩾ 5 mm in diameter on the surface of the instruments) which shall be removed by means of an absorbent pad. Then place the instruments upside down on another tray and leave them to dry for at least 30 min but not more than 60 min.

A.7.2 Instruments for minimally invasive surgery

Allow the blood to equilibrate to room temperature before use. Fill the lumens with the test soil in a way that the inner surfaces are completely wetted. Take care that the blood is used within approximately 10 min (in any case before complete coagulation). Make sure that the lumens are open after this procedure (e.g. by blowing through the lumens with compressed air). Then, apply a thin layer of blood to the outer surfaces of the dummies using a paintbrush.

Connect the soiled dummies to the appropriate nozzles and luer-locks (at least three per connection type) and place them on or in the load carrier according to the manufacturer's instructions.

All instruments shall be prepared and arranged on the load carrier within 30 min.

Leave the instruments on the load carrier to dry for at least 60 min but not more than 90 min.

A.8 Test method

A.8.1 Ordinary surgical instruments

Load the WD with the test instruments on their tray and start the WD with a full load. Run the cleaning cycle of the "surgical instrument" programme in accordance with the manufacturer's instructions.

Immediately after the cleaning cycle, interrupt the programme and unload the WD.

For each type of load, at least three cycles shall be run in the WD.

If there are not enough test instruments available to provide a full load, run as many cycles as necessary to check every position possible in the WD and fill the blank positions with clean items on their trays according to the manufacturer's instructions.

In addition, suitable industrially produced cleaning-indicators may be used which should be placed on the trays and evaluated after completion of the cleaning cycle in accordance with the manufacturer's instructions.

A.8.2 Instruments for minimally invasive surgery

Load the WD with test instruments and start the WD with a full load. Run the cleaning cycle of the adequate programme in accordance with the manufacturer's instructions.

Immediately after the cleaning cycle, interrupt the programme and unload the WD.

For each type of load, at least three cycles, shall be run in the WD.

Blank nozzles shall be connected to clean items according to the manufacturer's instructions.

In addition, suitable industrially produced cleaning-indicators may be used. At least one of them should be connected to each type of connection nozzle and evaluated after completion of the cleaning cycle in accordance with the manufacturer's instructions.

A.9 Results

A.9.1 Ordinary surgical instruments

A.9.1.1 Detection of residual soil

After cleaning in the WD, examine the instruments visually. Examine every single instrument by opening and closing box locks and joints. Record the number of clean (no remains of blood visible to the naked eye at normal light with any optical corrections required for normal visual acuity) and not clean instruments. Calculate the ratio of the test pieces with residual soil to the originally soiled instruments. Express the result in percent.

Items other than the inoculated test pieces shall not be considered.

In cases of doubt, protein detection tests (e.g. biuret reaction) should be carried out to confirm whether the visible residue is due to the test soil.

If applicable, examine the cleaning-indicators and check the results for compliance with the manufacturer's instructions.

A.9.1.2 Acceptance criteria

The cleaning efficacy of the WD shall be regarded as satisfactory if

— at least 95 % of all test pieces show no visible residue of the test soil,

— the amount of protein on the instruments is below the detection level or within the limits of the acceptance criteria given by the manufacturer of the test as applicable (see also ISO 15883-1:2005, Annex C),

— the results of the cleaning-indicators are within limits of the acceptance criteria of the manufacturer, if applicable.

A.9.2 Instruments for minimally invasive surgery

A.9.2.1 Detection of residual soil

Examine the outer surfaces of the instruments for minimally invasive surgery visually (see above). Record the number of clean (no remains of blood visible to the naked eye at normal light with any optical corrections required for normal visual acuity) and not clean instruments.

In addition, examine the inner surfaces by swabbing the tubes and examining the swabs for visible contamination. If no contamination is visible, check the swab for protein with protein detection tests (e.g. biuret reaction). Evaluate the tests in accordance with the manufacturer's instructions.

Items other than the inoculated test pieces shall not be considered.

A.9.2.2 Acceptance criteria

The cleaning efficacy of the WD should be regarded as satisfactory if

— none of the test pieces show visible residue of the test soil on the outer surfaces,

— the amount of protein in the lumen instruments is below the detection level or within the limits of the acceptance criteria given by the manufacturer of the test as applicable (see also ISO 15883-1:2005, Annex C), and

— the results of the cleaning-indicators are within limits of the acceptance criteria of the manufacturer, if applicable.

A.10 Safety considerations

A.10.1 Personal protective equipment

When preparing the test soil, inoculating the test pieces, loading the inoculated test pieces into the WD or examining the processed devices for residual protein, the operator should wear a protective gown (or apron) and gloves.

A.10.2 Disposal

All chemicals and test soils can be disposed of as non-hazardous, non-clinical waste.

A.10.3 Environmental spillage

Environmental surfaces that have been contaminated with test soil shall be wiped clean using a cloth moistened with a solution of an appropriate detergent/disinfectant in accordance with local policies and procedures.

Annex B
(normative)

Test soil and method for anaesthesia equipment (Austria)

B.1 Reference

The MNE[2)] test soil for testing and evaluating the cleaning efficacy of automated WDs for anaesthesia equipment is described in Reference [36].

B.2 Materials

— **Nigrosine** (1 % aqueous suspension).

— **Wheat flour**.

— **Hens' eggs**.

B.3 Apparatus

— **Normal laboratory apparatus.**

— **Paintbrush**, 25 mm in width.

— **Syringes** (20 ml or more).

B.4 Preparation of test soil

B.4.1 Nigrosine suspension

Add 6 g nigrosine powder to 600 ml lukewarm tap water, heat the mixture to approximately 80 °C and dissolve while stirring continuously.

B.4.2 Wheat flour suspension

Add 115 g of wheat flour to 800 ml cold tap water, heat while stirring continuously; bring to the boil and boil for 3 min.

B.4.3 MN mixture

Mix 600 ml nigrosine suspension (B.4.1) with 800 ml of wheat flour suspension (B.4.2).

This mixture may be prepared in larger amounts.

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2) MNE from German: Mehl, Nigrosin, Ei.

B.4.4 Completion of the test soil

Immediately before use, warm up 700 g of the MN mixture (B.4.3) to approximately 35 °C. Add the white and yolk of three middle sized raw eggs and mix thoroughly (MNE mixture). Allow the test soil to equilibrate to room temperature before use. Adjust to room temperature again, if necessary.

B.5 Storage

The test soil base (B.4.3) can be stored in a refrigerator and may be kept for up to 3 days.

B.6 Test pieces

— **Anaesthesia equipment**, of the type to be used in routine practice in sufficient numbers to provide a full load of the WD under test (preferably transparent/translucent tubing).

B.7 Inoculation of test pieces

If the soil has been stored, allow it to equilibrate to room temperature before use. Clean and dry the test pieces thoroughly. Apply the soil to the inner surface of the larger test pieces (breathing tubes, etc.) by pouring the soil into the items or using a syringe; place the test pieces on a horizontal surface and roll them to distribute the soil over the inner surface. Hold the test pieces vertically to allow excess soil to drain off the surface. Then, apply an even layer of the test soil to the outer surface using the paintbrush. Smaller test pieces, such as endotracheal tubes and connectors, should be treated similarly.

The complete anaesthesia equipment shall be prepared and arranged on the load carrier within 30 min.

Leave the soiled equipment on the load carrier to dry at ambient temperature and humidity for at least 60 min but not more than 90 min.

B.8 Test method

Load the WD with the test pieces and start the WD with a full load. Run the cleaning cycle of the relevant programme in accordance with the manufacturer's instructions.

Immediately after the cleaning cycle interrupt the programme and unload the WD.

For each type of load at least two cycles shall be run in the WD.

B.9 Results

B.9.1 Detection of residual soil

Examine the outer and inner surfaces of the test pieces visually. Report the number of clean (no remains of test soil visible to the naked eye at normal light with any optical corrections required for normal visual acuity) and not clean test pieces.

In addition, examine the inner surfaces as far as possible by swabbing the tubes and examining the swabs for visible contamination. If no contamination is visible, check the swab for protein with protein detection tests (e.g. biuret reaction). Evaluate the tests in accordance with the manufacturer's instructions.

Items other than the inoculated test pieces shall not be considered.