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Washer-disinfectors —

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

Laveurs désinfecteurs —

Partie 4: Exigences et essais pour les laveurs désinfecteurs destinés à la désinfection chimique des endoscopes thermolabiles

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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.

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 15883-4 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*

Introduction

It is recommended that this introduction be read in conjunction with the introduction to ISO 15883-1.

The washer-disinfectors specified in this part of ISO 15883 are intended to process devices which can be immersed in water or aqueous solutions. For some devices this will require that, prior to processing, relevant parts of the device are protected from immersion in accordance with the device manufacturer's operating instructions.

Fields of application within the scope of the ISO 15883 series include laboratory, veterinary, dental and pharmaceutical applications and other specific applications, such as washer-disinfectors for bedsteads and transport carts and the disinfection of crockery and cutlery intended for use with immunologically compromised patients.

Requirements for washer-disinfectors for other applications are specified in other parts of ISO 15883.

Safety requirements for washer-disinfectors are given in IEC 61010-2-040.

With respect to the potential adverse effects on the quality of water intended for human consumption caused by the washer-disinfectors:

a) note that, until verifiable European criteria are adopted, existing national regulations concerning the use and/or the characteristics of the washer-disinfectors remain in force;

b) this part of ISO 15883 provides no information as to whether the washer-disinfectors may be used without restriction in any of the member states of the EU or EFTA.

Washer-disinfectors —

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

1 Scope

This part of ISO 15883 specifies the particular requirements, including performance, for washer-disinfectors (WDs) that are intended to be used for cleaning and chemical disinfection of thermolabile endoscopes.

This part of ISO 15883 also specifies the performance requirements for the cleaning and disinfection of the washer-disinfector and its components and accessories which may be required to achieve the necessary performance.

The methods, instrumentation and instructions required for type testing, works testing, validation (installation, operational and performance qualification on first installation), routine control and monitoring and re-validation, periodically and after essential repairs, are also specified.

NOTE 1 In addition, Annex A gives guidance on an appropriate division of responsibility for the range of activities covered by this part of ISO 15883.

NOTE 2 WDs complying with this part of ISO 15883 can also be used for cleaning and chemical disinfection of other thermolabile re-usable medical devices for which the device manufacturer has recommended this method of disinfection.

WDs complying with the requirements of this part of ISO 15883 are not intended for cleaning and disinfection of medical devices, including endoscopic accessories, which are heat stable and can be disinfected or sterilized by thermal methods (see ISO 15883-1:2006, 4.1.5).

The specified performance requirements of this part of ISO 15883 may not ensure the inactivation or removal of the causative agent(s) (prion protein) of transmissible spongiform encephalopathies.

NOTE 3 If it is considered that prion protein might be present, particular care is needed in the choice of disinfectants and cleaning agents to ensure that the chemicals used do not react with the prion protein in a manner that may inhibit its removal or inactivation from the load or washer-disinfector.

This part of ISO 15883 can be used by prospective purchasers and manufacturers as the basis of agreement on the specification of WD manufacturers of endoscopes, cleaning products, disinfecting products, and also by users.

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 11731-2, *Water quality — Detection and enumeration of Legionella — Part 2: Direct membrane filtration method for waters with low bacterial counts*

ISO 15883-1:2006, *Washer-disinfectors — Part 1: General requirements, terms and definitions and tests*

ISO/TS 15883-5:2005, *Washer-disinfectors — Part 5: Test soils and methods for demonstrating cleaning efficacy*

IEC 61010-2-040, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 15883-1 and the following apply.

3.1
air break
physical separation in water supply pipes to prevent back syphonage into the water supply from a device connected to it

NOTE See EN 1717.

3.2
inoculated carrier
supporting material on or in which a defined number of viable test organisms has been deposited

[ISO 11138-1:2006, definition 3.10]

3.3
leak test
test intended to establish that the surface covering the device and/or lining a device channel is intact to the extent necessary to maintain a slightly positive pressure

3.4
liquid transport systems
those components of the washer-disinfector used to store, pump or transport water and/or solutions within the washer-disinfector, excluding pipework before the air break

3.5
microbial inactivation factor
measured change in microbial population, expressed as $\log_{10}$, caused by the lethal effect of the disinfectant

3.6
microbial reduction factor
measured change in microbial population expressed as $\log_{10}$ caused by the combination of the microbial inactivation factor and the physical removal of microorganisms

3.7
obstruction
partial or complete blockage

3.8
self-disinfection cycle
operating cycle under the control of the automatic controller, for use without any load in the washer-disinfector, which is intended to disinfect all liquid transport systems' piping, chamber(s), tanks and other components which come into contact with the water and/or solutions used for cleaning, disinfecting and rinsing the load

NOTE This does not include disinfection of any pipework between the disinfectant supply and the control valve, where single-use, multi-dose containers are used to provide process chemicals for use in the washer-disinfector.

3.9
thermolabile
damaged by exposure to temperatures within the range used for thermal disinfection

NOTE The minimum temperature for thermal disinfection specified in ISO 15883-1 is 65 °C.

4 Performance requirements

4.1 General

4.1.1 The WD shall conform to ISO 15883-1:2006 with the exception of the following subclauses:

— 4.2.3 (washing stage);

— 4.3.1 (specification for thermal disinfection);

— 5.3.2.5 (microbial quality of final rinse water);

— 6.4.2 (test for quality of final rinse water);

— 6.5.6 (test for chamber venting to prevent pressurization by steam);

— 6.7.2 (tests on trolleys for handling loads outside the WD);

— 6.8.2 (load temperature test);

— 6.10 (cleaning efficacy test; 6.10.2 modified by 6.11 of this part of ISO 15883).

NOTE These subclauses have been replaced or modified in this part of ISO 15883.

4.1.2 Each device, including any device channels and/or cavities, shall be processed by the WD as follows:

a) leak testing (where appropriate) in accordance with 4.2;

b) cleaning (which may include several stages) in accordance with 4.3;

c) disinfecting in accordance with 4.4;

d) final rinsing in accordance with 4.5;

e) purging of rinse water in accordance with 4.6;

f) drying (when appropriate) in accordance with 4.7.

4.1.3 After the complete process in the WD the endoscope shall be free from vegetative bacteria (but not necessarily spores) and other contamination. The combination of the cleaning process and the disinfection process shall be designed to achieve this condition, recognising the high level of bacterial contamination that may exist, see Bibliography [24], [25] and [26]. It shall be necessary to take into account other factors such as the design of connectors. The WD manufacturer shall demonstrate this capability during type testing for all the types of endoscope that the WD is designed to process.

NOTE 1 Demonstration of the capability of the complete cycle may be provided during type testing by employing a modification of the method described in Annex B, using the organism previously established as most resistant to the disinfectant, with real endoscope(s) and/or the method given in ISO/TS 15883-5:2005, Annex I.

NOTE 2 The efficacy of the process (including cleaning and disinfection) depends on a number of factors which include

a) the nature (characteristics) of the device being processed;

b) the extent and nature of the soiling to be removed;

c) the temperature;

d) the mechanical energy (type, output);

e) purging to remove rinse water;

f) the detergent system;

g) the nature, volume, concentration and temperature of the cleaning and disinfectant solutions and their ability to wet the surfaces to be cleaned and disinfected;

h) the duration of the various process stages;

i) the removal of suspended soil.

4.1.4 The WD manufacturer's instructions shall recommend that any requirements, e.g. for manual cleaning and or disassembly of the endoscope, prior to processing in the WD, provided by the device manufacturer should be followed.

4.1.5 The value of any process variable that affects the efficacy of the cycle shall be pre-set and adjustment shall require the use of a key, code or tool (see also ISO 15883-1:2006, 5.18.3, 5.18.8 and 5.18.12).

4.1.6 The means to control the volume of process chemicals admitted shall deliver the set volume to an accuracy of $\pm$ 5 % or better.

4.1.7 When the WD uses two or more different process chemicals, means shall be provided to ensure that connection is made to the correct container of process chemical.

NOTE The labelling and/or colour coding of connectors, containers and/or tubes alone may not be sufficient to meet the requirement.

4.1.8 The WD manufacturer's instructions shall recommend that heat-stable endoscopic accessories to thermolabile devices should be thermally disinfected and/or sterilized. [See 8 j) and ISO 15883-1:2006, 4.1.5].

4.2 Systems for leak testing

4.2.1 The requirements of 4.2 shall apply only to WDs intended to process endoscopes which require a test to verify that the device is watertight.

NOTE This test is intended to demonstrate that the endoscope will not be damaged by liquid ingress during the WD operating cycle. It is regarded only as a test of the integrity of the endoscope when all parameters of the WD leak test (e.g. pressure, duration, maximum leak accepted) are consistent with those specified by the endoscope manufacturer.

4.2.2 The WD shall be provided with either

a) means to carry out an automatic leak test on the endoscope which shall be completed before the load comes into contact with process fluids in the WD

or

b) instructions for use that include the requirement to carry out the test manually prior to processing through the WD.

NOTE 1 An alternative method specified by the endoscope manufacturer can be used for determining the integrity of the endoscope when appropriate.

NOTE 2 WDs with an automatic leak test can include a user selectable option to repeat the leak test at the end of the process and/or independently of a normal process cycle.

4.2.3 For WDs having an automatic leak test, the automatic controller shall prevent the continuation of the operating cycle and operate an audible and visible alarm indicating a leak test failure if a leak is detected in an endoscope.

Variations in temperature may adversely affect the sensitivity of the leak test and the WD manufacturer should state the temperature range permitted in the WD during the automatic leak test, if fitted [see 8 f)].

NOTE 1 A leak test failure indicates that the device is likely to be damaged by further processing; a satisfactory leak test does not provide absolute assurance that the device will not be damaged by further processing.

NOTE 2 An automatic leak test which maintains a positive pressure throughout the cycle can provide an additional safety level.

4.2.4 In WDs provided with an automatic leak test:

— the systems for connection of the device to the WD shall be designed so that the fittings provided by the WD manufacturer and intended for irrigation of the endoscope channel(s) cannot be connected to the endoscope leak test connector;

— the connection system between the endoscope and the WD shall be designed so that the leak test connector on the WD cannot be connected to the endoscope channel(s) to be irrigated;

— the means used to monitor the pressure inside the device (e.g. pressure transducer) shall be independent from the means used to control the initial pressure (e.g. pressure regulating valve);

— the system used to pressurize the device during each leak test shall be provided with a means of preventing over-pressurization of the device in the event of failure of the pressure control system;

— the extent and duration of pressurization and the pressure drop or air flow which will be used to indicate a failure shall be either in accordance with the device manufacturer's instructions for the devices which the WD is intended to process, or independently verified by the WD manufacturer.

4.2.5 For WDs with an automatic leak test, means shall be provided to automatically warn the user with an audible and/or visible alarm after the initiation of the operating cycle if the leak test connectors were not connected to the endoscopes.

4.2.6 WDs with an automatic leak test shall be tested in accordance with 6.5.

4.3 Cleaning

4.3.1 General

All surfaces (internal and external) of the endoscope(s) which are required to be disinfected by the WD shall be cleaned. (See ISO 15883-1:2006, 4.2.1.1, 5.1.10 and 6.10.2).

NOTE Some endoscope(s) have component parts (e.g. electronic connectors) which their manufacturer recommends should not be immersed in water or aqueous solutions. These component parts will be processed in accordance with the manufacturer's instructions and then protected from immersion during processing in the WD (see 5.1.2).

Cleaning shall comprise washing with a detergent solution which may, when necessary, be preceded by flushing. Washing shall be followed by rinsing unless the conditions specified in 4.3.4 have been met.

4.3.2 Flushing

When necessary, the WD shall provide means to flush the internal and external surfaces of the endoscope.

NOTE Flushing before washing might be necessary to eliminate soils or to avoid any interaction between the chemicals used during pre-treatment and those of the WD processing cycle.

The flushing water or solution shall be discharged during or after each process cycle and shall not be re-used.

4.3.3 Washing

The WD manufacturer shall specify the detergent(s) to be used, as established during type testing [see 8 m)].

The detergent solution shall be discharged during or after each process cycle and shall not be re-used.

The temperature of the detergent solution throughout the washing stage shall be monitored to ensure that it remains within the limits specified by the manufacturer of the detergent and be compatible with the temperature limits for the device(s) to be processed.

This shall be achieved either

a) by controlling the temperature of the detergent solution

or

b) where appropriate, by operating the WD at ambient temperature with a means of preventing operation of the WD when the detergent temperature is outside the specified temperature range.

4.3.4 Post-washing rinsing

Rinsing between washing and disinfection shall be used to reduce the concentration of residues (process chemicals and soiling including microbial contamination) to a level established as not exceeding that which would impair the efficacy of the disinfection process.

Rinsing shall take place between washing and disinfection unless it can be demonstrated that:

a) there is no reaction between incompatible process chemicals being used for each of these phases;

b) there is no adverse reaction between suspended or residual soiling and the disinfectant.

The interaction between the disinfectant and residual soiling shall be tested under conditions in which soiling is at or above the maximum level that may occur in use and the disinfectant is at or below the minimum specified in-use concentration.

The rinse water quality shall be specified by the WD manufacturer; this shall be of, at least, potable quality.

4.3.5 Determination of cleaning efficacy

Cleaning efficacy shall be determined in accordance with 6.11.

4.4 Disinfecting

4.4.1 General

National regulatory requirements may specify approval procedures for disinfectants to be used in WDs for medical devices. Compliance with these national requirements shall be deemed to meet the requirements of 4.4 within the territory where these requirements apply.

The capability of the WD to provide disinfection of the device shall be deemed to have been established if, when the WD is tested as specified in 6.12.6 under the specified conditions of disinfectant concentration, volume, temperature and contact time the required microbial inactivation factor is attained (see 4.4.2.4).

The choice of disinfectant shall ensure that the spectrum of activity is appropriate for the intended use. The efficacy of disinfectants may be seriously impaired by residual soiling, inorganic salts etc. remaining on the device(s) and therefore an effective cleaning prior to disinfection is required.

NOTE Other process chemicals, e.g. detergents can react with and seriously impair the activity of disinfectants if they are not removed before the disinfection stage.

4.4.2 Efficacy of the disinfectant

4.4.2.1 The following tests are based on the use of aqueous solutions of a disinfectant. Other systems based on gaseous disinfectants are not excluded; equivalent tests are required.

4.4.2.2 When tested in accordance with 6.12.2, the *in vitro* efficacy of the disinfectant shall be demonstrated.

4.4.2.3 A specific neutralization method for the disinfectant shall be validated in accordance with 6.12.2.6.

NOTE These data can be provided by the disinfectant manufacturer.

4.4.2.4 When tested in accordance with 6.12.2 and 6.12.6 for the minimum exposure time at the minimum concentration and the minimum temperature to be used in the WD the disinfectant shall demonstrate:

a) at least a $\log_{10}6$ inactivation of vegetative bacteria including yeasts and yeast-like fungi;

b) at least a $\log_{10}5$ inactivation of mycobacteria;

c) at least a $\log_{10}4$ inactivation of fungal spores and viruses.

NOTE 1 The inactivation values specified are regarded as the minimum necessary for endoscopes; they may be different from the values specified in other standards to permit a label claim for biocidal activity.

NOTE 2 National regulatory authorities can require higher inactivation values.

4.4.2.5 The disinfectant chosen shall also be active against bacterial endospores.

When tested at the minimum concentration and the minimum temperature to be used in the WD when processing endoscopes, the disinfectant should reduce the population of bacterial spores by not less than $\log_{10}6$ within 5 h of exposure, or at an equivalent rate. The disinfectant should be tested against spores of known high resistance to the disinfectant from both aerobic and anaerobic organisms.

4.4.2.6 The experimental conditions of tests intended to demonstrate the microbicidal activity of the disinfectant *in vitro* shall consider the conditions of use of the disinfectant. Thus, when there is no rinsing between cleaning and disinfection, the disinfectant shall be tested in the presence of interfering substances (see also 4.3.4), and, for example, dirty conditions.

NOTE Demonstration by the disinfectant manufacturer that the disinfectant meets the above requirements may be made employing methods based on relevant published standards or other relevant publications (e.g. EN 13624, EN 13727, EN 14348, EN 14476, EN 14561, EN 14562, AOAC sporicidal test, ASTM E2111-00).

4.4.3 Temperature

The temperature of the disinfectant solution throughout the disinfection stage shall be monitored to ensure that it remains within the limits specified by the manufacturer of the disinfectant and be compatible with the temperature limits for the device(s) to be processed.

This shall be achieved either by controlling the temperature of the disinfectant solution or, where appropriate, by operating the WD at ambient temperature with means to prevent operation of the WD when the disinfectant temperature is outside the specified temperature range.

4.4.4 Process monitoring

The process monitoring of each operating cycle by the automatic controller shall include verification that the process conditions specified by the WD manufacturer as necessary and sufficient for disinfection to take place (e.g. disinfectant concentration, temperature and contact time) were attained (see also 5.5).

Microbial testing (e.g. with biological indicators or inoculated carriers) of the disinfection stage on each cycle shall not be used to meet this requirement.

NOTE Confirmation of the concentration of disinfectant can require e.g. measurement of the volume of disinfectant and water admitted together with a certificate of conformity from the disinfectant supplier for the concentration of the disinfectant, together with data to support the shelf life, expiry date etc. (see also 4.4.5.2).

4.4.5 Disinfectant use

4.4.5.1 General

The WD manufacturer shall specify the disinfectant(s) to be used, as established during type testing (see 8 m).

Disinfectant solutions shall either be discharged after a single use during each cycle or re-used for a limited number of cycles (see 4.4.4). Discharge after a single use, during each cycle, is the preferred option.

4.4.5.2 Re-use of disinfectant solutions

If the WD is designed to allow the same disinfectant solution to be used on two or more consecutive operating cycles then care shall be taken to ensure that the activity and safety (e.g. accumulation of foreign material, device compatibility) of the disinfectant solution is not impaired during its working life.

This shall include the following.

a) The WD manufacturer shall specify the means which shall be used to ensure that the disinfectant solution has retained the required anti-microbial activity. These means shall be based on validation studies, which would normally be carried out by the disinfectant manufacturer, to determine a suitable parameter, or parameters, which may be monitored to indicate the anti-microbial activity of the disinfectant. Suitable parameters may include e.g. pH, stability, the concentration of the active ingredient and adjuvants that may also affect performance.

NOTE Minor changes in formulation of the disinfectant can have a significant effect on storage life, anti-microbial activity etc.

b) The WD manufacturer shall recommend to the user the maximum period or number of operating cycles for which the disinfectant may be used. This shall be based on validated experimental data.

c) When validated use conditions (maximum period or number of operating cycles) are exceeded, the automatic controller shall operate an audible and visible alarm and prevent the use of the operating cycle until chemicals are changed.

The WD manufacturer should recommend that the user monitor the disinfectant concentration using a chemical indicator specific for the disinfectant to show that the disinfectant is at or above the minimum recommended concentration (see also 4.4.4).

4.5 Final (post-disinfection) rinsing

4.5.1 The chemical purity of the final rinse water used after the disinfection stage shall be in accordance with ISO 15883-1:2006, 5.3.2.5.

4.5.2 The final rinse water shall meet the requirements for microbiological quality as given in 4.9.2.2.

4.5.3 When medical devices that are intended to come into contact with the bloodstream or other normally sterile areas of the body are to be processed the level of bacterial endotoxins in the final rinse water shall be controlled and monitored within the limits specified in national regulations. (See ISO 15883-1:2006, 6.4.2.3).

4.5.4 On completion of the final rinse stage the water shall not be stored for subsequent re-use in the rinsing stage of subsequent cycles.

4.6 Purging to remove rinse water

4.6.1 The WD shall include a means of purging rinse water from the channels of the endoscope(s) at the end of the final rinse stage.

NOTE On completion of the automatic cycle the outer surface of the device should not have so much surface water that it would need to be wiped dry before use.

4.6.2 When at the end of the rinsing stage the channels of the device are purged with air to remove most of the remaining rinse water, the air shall be oil free and shall be filtered through a filter providing not less than 99,99 % arrestance to particles of 0,2 µm and larger.

4.6.3 When the WD is intended to eliminate the residual water from the channels of the endoscope it shall be tested in accordance with 6.8.

4.7 Drying

4.7.1 Either the WD shall have a user selectable drying stage, or the instructions for use shall indicate that the device and the channels of the device shall be dried prior to storage in accordance with the device manufacturer's instructions [see 8 j), 2nd dash].

NOTE 1 Automatic cycles in which the device is not completely dried are intended for use with devices which will be used without storage. Storage of incompletely dried devices can lead to contamination with, and growth of, micro-organisms.

NOTE 2 Purging with 0,2 µm filtered alcohol (e.g. 70 % iso-propanol) can be used to aid drying, if compatible with the device.

4.7.2 The quality of air used during the drying stage shall be at least that defined in 4.6.2.

4.7.3 When tested in accordance with 6.8 there shall be no visible droplets of moisture.

4.8 Self-disinfection

4.8.1 A self-disinfection cycle shall be provided to ensure that the WD does not become a focus for contamination of the load and to provide a means of disinfecting the WD after interventions for maintenance, repairs or testing (see also ISO 15883-1:2006, 5.3.1.2).

NOTE 1 The self-disinfection process is intended also to deal with the situation where the WD has become contaminated. The piping used to convey rinse water to the endoscope, if contaminated, can easily develop a layer of biofilm containing many microorganisms in a state in which they are highly resistant to chemical disinfection.

NOTE 2 Thermal disinfection using moist heat is the preferred method. The temperature used can be higher than the normal maximum operating temperature available for the loaded WD.

If the use of thermal disinfection is not possible, a disinfectant different from that used for disinfecting the endoscope should be used. The use of the same disinfectant carries the risk of allowing organisms resistant to that particular disinfectant to proliferate.

NOTE 3 Disinfection cannot be relied upon to inactivate all bacterial spores.

4.8.2 A WD in which the endoscope process cycle provides for disinfection of the chamber and all piping and tanks which come into contact with the water or solutions used for cleaning, disinfecting and rinsing the load shall be deemed to meet this requirement without the provision of an additional self-disinfection cycle.

4.8.3 The manufacturer shall provide details of the parts of the WD subjected to the self-disinfection cycle and whether this cycle includes the water treatment equipment (see 4.9).

4.8.4 When different from the normal operating cycle the WD self-disinfection cycle shall:

— be operated under the control of the automatic controller;

— be a user selectable cycle;

— provide for disinfection of the chamber and all liquid transport systems;

— include means to warn the user that the WD shall be operated without any load in the chamber and, so far as may be practicable, include means to verify that no device is present before the cycle will operate;

— in the case of thermal self-disinfection of the WD, ensure that all the parts of the heating system and the associated pipework, via which the water or the steam reach the WD tank, attain an A_0 value of at least 600.

4.8.5 The self-disinfection cycle shall ensure that a WD that has become contaminated through failure of the water treatment equipment can be effectively disinfected. Compliance shall be verified by testing in accordance with 6.12.5. The performance shall be deemed to be satisfactory if the final microbial count is 10 cfu/100 ml[1)] or fewer after carrying out a self-disinfection cycle.

4.8.6 Thermal disinfection systems shall be evaluated by thermometric monitoring of the system with sensors placed at those parts of the system specified by the WD manufacturer as representative of the lowest temperatures in the system. The entire system subjected to thermal disinfection shall attain the required disinfection temperature.

4.8.7 For chemical disinfection systems a microbiological test shall be required. The test shall be designed to ensure that the self-disinfection cycle will disinfect contaminated tubing by evaluating the effect of the cycle against a biofilm containing *Pseudomonas aeruginosa* (see ISO/TS 15883-5:2005, Annex F). The capability of the WD to provide self-disinfection shall be deemed to have been established if, when tested in accordance with 6.12.3, the required microbial reduction factor has been achieved.

1) cfu = colony forming units.

4.8.8 National regulatory requirements may specify approval procedures for validating self-disinfection of WDs for medical devices. Compliance with these national requirements shall be deemed to meet the requirements of 4.8 within the territory where these requirements apply.

4.9 Water treatment equipment

4.9.1 General

Means shall be provided to ensure that water treatment equipment that is part of the WD (softeners, de-ionizers, filters etc.) is operated within the limits (e.g. flow rates, supply pressures) specified by the manufacturer of the water treatment equipment.

4.9.2 Disinfection of water treatment equipment

4.9.2.1 When the water treatment equipment is a part of the WD, the former shall be designed and constructed so that it can be periodically submitted to a disinfection procedure. Guidance on the minimum frequency with which the equipment shall be disinfected shall be stated by the WD manufacturer according to the information supplied by the purchaser for the quality of the water supply and the manufacturer of the water treatment equipment [see 8 n)].

NOTE The disinfection of the water treatment equipment can be carried out during a self-disinfection cycle.

The actual frequency should be decided by the user based upon known, e.g. seasonal, variations in the quality of water supplied to the WD and the operational history of the water treatment equipment.

The disinfection method shall not cause any damage to, nor impair the efficacy of, the treatment equipment.

The efficacy of the water equipment disinfection procedure to provide self-disinfection shall be deemed to have been established if, when tested in accordance with the methods given in 6.12.4 and 6.12.5 there shall be less than 10 cfu recovered from each of two 100 ml samples and other controlling parameters have been achieved.

4.9.2.2 If the water treatment equipment is not part of the WD, the WD manufacturer shall specify the requirements for water supplied to the WD. This shall include specification of the permissible microbial contamination of the water supply [see 4.3.4 and 8 n)].

NOTE To meet the specification of the permissible microbial contamination of the water supply, it can be necessary for the user to make provision for disinfection of the external water treatment equipment.

Means shall be provided to disinfect incoming water used for the final rinse. The disinfection process shall ensure that

a) there are fewer than 10 cfu/100 ml sample of final rinse water;

b) the water is free from legionellae, *Pseudomonas aeruginosa* and *mycobacteria* (see 6.3).

NOTE The following methods can be suitable for control of the microbial contamination of rinse water. The rinse water will be:

— maintained in a dedicated reservoir at a temperature not less than 65 °C for the time demonstrated to achieve disinfection of the incoming supply

or

— disinfected immediately prior to use

or

— filtered to remove suspended particles of a size greater than 0,2 µm

or

— sterile, in a closed container, with a connection to the WD designed and constructed to provide aseptic transfer.

4.9.2.3 The connection between the water supply, which has been treated to remove microbial contamination and the circulation system for rinsing the endoscope shall be designed and constructed to provide aseptic transfer.

Provision shall be made for disinfection of this connection to be made periodically. The frequency and method of carrying out this disinfection shall be specified by the WD manufacturer.

4.9.2.4 From before the rinsing stage until the end of the processing cycle, as appropriate, the final water treatment used to fulfil the requirements of 4.5 shall be monitored by the WD automatic controller to verify that the parameters affecting the efficacy of the water treatment equipment remain within specification.

4.9.3 Maintenance of piping

The WD manufacturer shall specify the planned preventive maintenance required on the piping that is part of the WD and is used to convey final rinse water to the endoscope. This shall include the frequency at which such piping should be replaced.

5 Mechanical and process requirements

5.1 Materials — Design, manufacture and construction

5.1.1 The maximum temperature of any process fluid in contact with the load shall be controlled below the temperature that would cause degradation of the device(s) which the WD is intended to process (see ISO 15883-1:2006, 4.1.4).

5.1.2 The load carrier intended to accommodate the device(s) to be processed shall be designed and constructed to minimize the possibility of damage to the device(s) at the time of loading, during processing and during the course of unloading.

5.2 Device channel irrigation system

5.2.1 General

5.2.1.1 During at least part of each of the cleaning, disinfection and rinsing phases, the device channel irrigation system shall ensure that the various process fluids flow through each of the internal channels and/or cavities of the devices that are required to be cleaned and disinfected. Assurance that this has taken place shall be provided either by:

a) the automatic controller providing means to verify the flow of process fluids through each channel (see 5.2.2);

or

b) requiring in the instructions for use that the user:

— verifies that all channels allow the free passage of water before the device is loaded into the WD;

— confirms that all necessary connections were made before, and were still in place at the end of, the cycle;

— confirms by reference to the WD process record that the supply of process fluids was maintained during each stage of the process (see 5.5):

— verifies flow through each endoscope channel at the end of each operational cycle or immediately before use.

Option a) above is the preferred method. Before choosing equipment conforming with option b) users should consider the increased requirement for staff training, staff time during reprocessing and the lack of an independent record that the process was carried out in a satisfactory manner.

5.2.1.2 The WD manufacturer shall provide a diagram of the circulation pathway of the fluids for all channels of each medical device that the WD is intended to process (see 4.1.2) based on information from the manufacturer of each device [see 8 i)].

Where an endoscope is one of a “family” of essentially similar devices it shall be sufficient to provide a flow diagram for the “family” of endoscopes.

The flow diagram and/or instructions shall show any limitations on how, or to which port on the WD, the endoscope channels shall be connected.

5.2.1.3 The WD manufacturer shall specify the minimum and maximum flow and maximum pressure that the WD is designed to deliver to each channel or channel system. When the WD is intended to process a specific medical device the maximum pressure(s) and flow(s) specified by the device manufacturer shall not be exceeded.

In cases where different channels are irrigated at different pressures, the connection systems shall be designed to prevent incorrect connections.

5.2.2 Verification of device channel irrigation by the automatic controller

5.2.2.1 The WD manufacturer shall specify for each channel the maximum extent of flow reduction permissible (e.g. change in flow volumes, pressures, rates, etc.) that will not impair the efficacy of the process [see 8 a)].

The WD manufacturer should request the device manufacturer to supply relevant data e.g. dimensions of connectors, internal dimensions of channels, maximum pressures to which channels may be subjected, in order to enable the WD manufacturer to determine the flow that will occur through the unobstructed channels.

When one or more channels of the device are obstructed to an extent that would impair the efficacy of the process, the automatic controller shall cause a fault to be indicated.

Compliance with this requirement shall be demonstrated by testing in accordance with 6.6.

With some designs of endoscope a blockage in one channel may cause the flow to be diverted to another channel or port. Under these circumstances detection of an obstruction by the automatic controller may not be reliable. The user should refer to the device manufacturer’s instructions for the method to be used to verify that all channels are free from obstructions.

5.2.2.2 When one or more channels of the device are not connected to the WD, the automatic controller shall cause a fault to be indicated.

Compliance with this requirement shall be demonstrated by testing in accordance with 6.7.

5.2.2.3 The automatic controller shall verify that the duration of flow of the relevant process fluids met or exceeded the minimum exposure times established during validation studies as necessary for each process stage. Failure to achieve the required flow shall cause a fault to be indicated.

5.2.2.4 When there is a common connection for fluid at the same supply pressure to more than one channel, the WD manufacturer shall provide evidence that the flow through each of the channels meets, or exceeds, the minimum required for effective cleaning, disinfection and rinsing of each device channel to be processed.

5.3 Venting and drainage systems

The WD shall be designed and constructed to ensure that there is no noxious discharge (see IEC 61010-2-040).

NOTE Attention is drawn to local regulations concerning the concentration of process chemicals discharged to waste.

5.4 Temperature control

5.4.1 General

Throughout the operating cycle, when tested as specified in 6.9.1, the temperature recorded on the surface of the chamber and on all surfaces of the device being processed shall be within the operating temperature range specified by the WD manufacturer for each stage of the operating cycle.

5.4.2 Temperature control of the washing stage

Throughout the washing stage, when tested as described in 6.9.1, the temperature recorded on the surface of the chamber and on all surfaces of the device being processed shall be within 0 °C to 5 °C of the washing temperature specified by the WD manufacturer (see ISO 15883-1:2006, 4.2.3).

5.4.3 WDs with thermostatic control of the disinfection stage

Throughout the disinfection stage, when tested as described in 6.9.1, the temperature recorded on the surface of the chamber and on all surfaces of the device being processed shall be within 0 °C to + 5 °C of the disinfection temperature specified by the WD manufacturer.

5.4.4 WDs with a minimum operating temperature for the washing and/or disinfection stage

Throughout the washing and/or disinfection stage, when tested as described in 6.9.2, when the temperature on the surface of the chamber and of the liquid process medium are below the minimum temperature specified by the device manufacturer a fault shall be indicated.

5.5 Process chemicals

The conditions of use (temperature, concentration etc.) within the WD for all process chemicals (detergent, disinfectant etc.) shall be within the limits specified by the process chemical manufacturer.

Where required for testing purposes the WD manufacturer shall obtain from the process chemical manufacturer the method(s) to be used to neutralize the process chemical (e.g. to stop any further anti-microbial activity) and shall make this information available to the user (see 4.4.2.3, NOTE).

5.6 Process verification

Process verification shall be in accordance with ISO 15883-1:2006, 5.11.4 c).

5.7 Dosing systems

For those WDs in which the required dose of process chemical is contained in a single-dose container which is replaced before each cycle, means shall be provided to ensure that the intended volume has been dispensed.

Compliance shall be tested in accordance with 6.10.

For WDs in which process chemicals are supplied in multi-dose containers, ISO 15883-1:2006, 5.7 applies.

6 Testing for conformity

6.1 General

The tests described in this section are in addition to the tests described in ISO 15883-1 and are specific for WDs intended to process thermolabile endoscopes. They are reference tests intended for use in demonstrating compliance with the specified requirements of this part of ISO 15883. They may be used in type tests, works tests and in validation and re-qualification tests, or in routine tests carried out by, or on behalf of, the user. Other tests and methods providing equivalent assurance may be used by the manufacturer as the basis of claiming compliance with this part of ISO 15883. In any case of dispute the reference tests given in this part of ISO 15883 shall be used.

The summary programme of tests in addition to those given in ISO 15883-1 is shown in Annex C.

NOTE A number of the tests can be carried out simultaneously with each other and/or with those required by IEC 61010-2-040.

6.2 Test equipment

6.2.1 General

The equipment specified is external to the WD and intended for use in testing the WD. The overall accuracy of the system chosen shall be such that the error is less than ± 2 % of the value to be measured unless otherwise specified for the specific measuring system.

6.2.2 Pressure measurement

The sensor and/or measuring system shall be temperature compensated.

The sensor error shall not exceed 0,25 % of full scale deflection.

The recorder for pressure measurement shall have an overall limit of error not exceeding 1 % of the maximum specified operating pressure for the variable being measured.

6.2.3 Flow measurement

6.2.3.1 Water

ISO 15883-1:2006, 6.4.4 applies.

6.2.3.2 Process Chemical

ISO 15883-1:2006, 6.9 applies.

6.3 Water used for final (post-disinfection) rinsing

The water used for final (post-disinfection) rinsing shall conform to ISO 15883-1:2006, 6.4.2.4. In addition, it shall be tested for total viable count and also for the presence of legionellae, *Pseudomonas aeruginosa* and *mycobacteria* at the point of discharge into the WD chamber in accordance with Annex E.

Results shall be reported as the number of colony forming units per 100 ml of water for the total viable count and the presence or absence of *legionellae*, *Pseudomonas aeruginosa* or *mycobacteria*.

It is recommended that the test be carried out prior to installation and at least annually thereafter. The tests specified in ISO 15883-1:2006, 6.4.2.4 should also be carried out prior to initial installation and at regular intervals thereafter. This may be approximately weekly until it has been established that the water supply is consistently within specification and at more extended intervals thereafter.

NOTE 1 Tests for other organisms that can be of clinical significance (e.g. *Acinetobacter*) may need to be performed.

NOTE 2 Where there may be residual detergent or disinfectant present it can be necessary to use a neutralization method to eliminate any anti-microbial activity (see 5.5).

6.4 Hardness of water used during type testing

6.4.1 If the WD manufacturer specifies the limit of hardness for water supplied to the WD (see ISO 15883-1:2006, 5.23.1), type tests shall be performed using water of the hardness specified.

6.4.2 When no limit is specified by the WD manufacturer, hard water for dilution of detergent or disinfectant products shall be prepared as follows and used as the water supply to the WD during type testing to verify conformity with this part of ISO 15883.

a) Solution A

- $MgCl_2$ anhydrous: 19,84 g;
- $CaCl_2$ anhydrous: 46,24 g;
- Sterile purified water: to 1 l;
- Sterilize at 121 °C, 15 min.

b) Solution B

- $NaHCO_3$: 35,02 g;
- Sterile purified water to 1 l;
- Sterilize by filtration.

Put not less than 600 ml of sterile purified water into a sterile 1 000 ml volumetric flask, add 6 ml of solution A and 8 ml of solution B and make up to 1 000 ml with sterile purified water.

Adjust the pH of the solution to (7,0 ± 0,2) using sodium hydroxide or hydrochloric acid as necessary.

When a solution containing 80 % of this test solution is prepared the final concentration shall be 300 mg $CaCO_3$/kg.

6.5 Leak test

6.5.1 General

This test is based on the use of a surrogate device.

NOTE The surrogate device might not adequately represent all possible types of endoscope.

6.5.2 Test equipment

6.5.2.1 **Test piece**, consisting of a length of tubing terminated at one end with a connector suitable for connection to the WD and at the other end with a flow control valve; the internal volume of the tube shall be within ± 10 % of the internal volume of the largest endoscope that the WD is intended to process.

6.5.2.2 **Pressure transducer**, capable of reading to ± 1 mbar (± 0,1 kPa) over the range of the system's operating pressure.

6.5.3 Procedure

6.5.3.1 Calibration

Verify the calibration of the pressure sensor.

6.5.3.2 Testing the pressure relief device

Connect the test piece (6.5.2.1) to the WD with the flow control valve fully closed. The pressure regulation system shall be disabled. Initiate the leak test. Record the pressure at which the pressure relief system operates, p_a. Continue operating until the pressure reading from the transducer (6.5.2.2) is steady and record the pressure, p_b. Verify that p_a and p_b do not exceed the maximum pressure specified by the WD manufacturer [see 8 c)].

6.5.3.3 Testing the leak rate test and indication of a leak

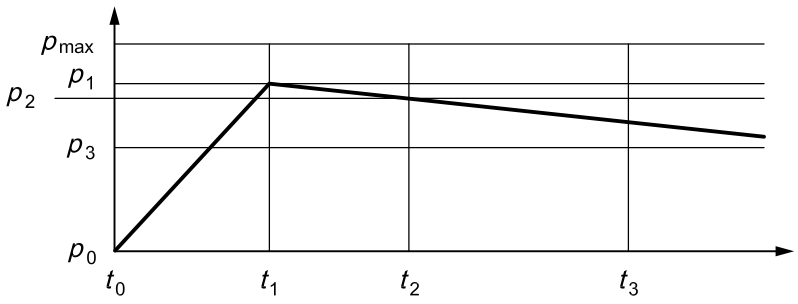
6.5.3.3.1 Fault condition

Adjust the flow control valve on the test piece to give a leak rate, at the leak test pressure, p_i, greater than that specified by the WD manufacturer. Connect the test piece to the WD and operate the leak test. Verify from readings taken from the pressure transducer that a fail condition has been produced. Verify that the WD indicates a fault.

6.5.3.3.2 Pass condition

Adjust the flow control valve on the test piece to give a leak, at a leak test pressure, p_i, that is 80 % of the fail value specified by the WD manufacturer. Connect the test piece to the WD and operate the leak test. Verify from readings taken from the pressure transducer that a pass condition has been produced. Verify that the WD indicates a pass.

The leak test criteria may be shown as a pressure/time graph as shown in Figure 1.



Key

p_0 atmospheric pressure
p_{max} pressure at or below which the pressure relief system should operate
p_1 pressure to which the endoscope is pressurized for the leak test
t_1 start of the leak test equilibration period
p_2 pressure after an initial equilibration period (optional)
t_2 start of the leak test pressure monitoring period
t_3 end of the leak test pressure monitoring period
p_3 pressure at the end of the leak test period
$\Delta p/t$ maximum rate of leakage permitted for processing to continue

NOTE With the pump, or other air supply, in continuous operation the pressure relief system prevents the endoscope being pressurized above p_{max}.

Figure 1 — Pressure versus time graph for leak test

Then:

$$\frac{(p_2 - p_3)}{(t_3 - t_2)} \leqslant \Delta p / t \text{ or } \frac{(p_1 - p_3)}{t_3 - t_1} \leqslant \Delta p / t \quad (1)$$

6.5.3.4 “Leak Test” for non connection

6.5.3.4.1 Procedure

Disconnect the port of the test piece from the WD. Initiate an operating cycle.

6.5.3.4.2 Results

Report whether or not a warning was indicated.

6.6 Channels non-obstruction test

6.6.1 General

The test is intended to determine the correct functioning of the system for detecting that channels within the device are not obstructed.

This test is based on the use of a surrogate device.

NOTE The surrogate device might not adequately represent all possible types of endoscope.

6.6.2 Test equipment

A surrogate device shall be used to simulate the medical device.

The surrogate device shall consist of endoscope trumpet valves in combination with three tubes of polytetrafluorethylene (PTFE), simulating the water channel (inner diameter of 2 mm, length 1 500 mm on both sides of the trumpet valve), the air channel (inner diameter of 2 mm, length 1 500 mm on both sides of the trumpet valve) and the biopsy/suction channel (inner diameter 4 mm, length 1 500 mm on both sides of the trumpet valve), 100 mm tube between the biopsy port and the suction valve. Additional tubes may be added to simulate the construction of particular endoscopes that the WD is intended to process. For example to simulate the elevator channel a separate tube of inner diameter 1 mm, with a stainless steel wire with an outer diameter of 0,7 mm, length 2 000 mm may be used. Figure 2 illustrates an example of a suitable surrogate device. Construction drawings of typical trumpet valves may be found in Annex F.

Each channel is provided with a means (e.g. Luer lock connectors) to place test pieces in the channels on the positions indicated in Figure 2. The test pieces can be used to limit the flow through the channels in the channel non-obstruction test. The test pieces can be contaminated with a test soil for the test of cleaning efficacy.

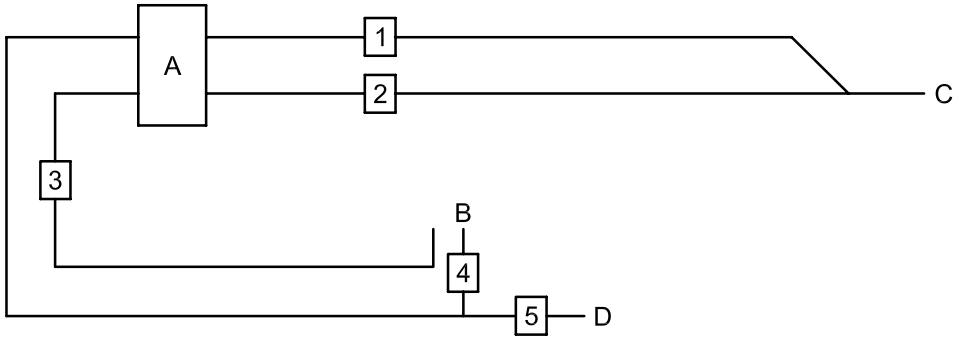
When specific connectors/separators are recommended by the WD manufacturer for the purpose of the channel non-obstruction test, the test shall be repeated with a specific surrogate device modified to include those specific connectors/separators.

6.6.3 Procedure

For WDs on which the automatic controller includes provision to detect obstructed channels (see 5.2.2) repeat the operating cycle with the surrogate device with one channel obstructed. Repeat this test so that each available channel in turn has been obstructed.

6.6.4 Results

Report whether or not a fault was indicated when each channel was obstructed.



a) Air/water channels

Key

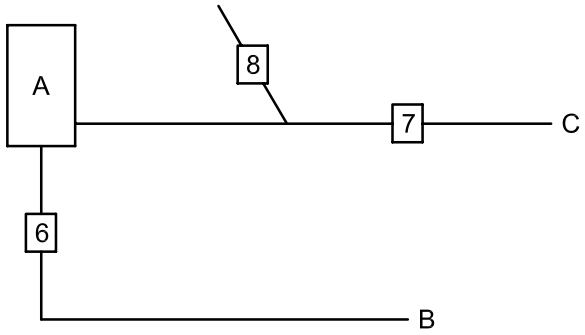
A air/water valve

B water bottle connector

C distal end

D air connector

1, 2, 3, 4, 5 positions of test pieces using connection points with minimal influence on the flow through the test pieces



b) Biopsy/suction channel

Key

A suction valve

B distal biopsy port

C distal end

6, 7, 8 positions of test pieces using connection points with minimal influence on the flow through the test pieces

Figure 2 — Examples of a suitable surrogate device for use in the channels' non-obstruction test, cleaning test or microbiological test

6.7 Channels non-connection test

6.7.1 Test equipment

A surrogate device similar to that described in 6.6.2 shall be constructed in which each tube is unobstructed at the distal end.

6.7.2 Procedure

For WDs on which the automatic controller includes provision to detect failure to connect channels (see 5.2.2), repeat the operating cycle with the non-obstructed surrogate device with one channel not connected. Repeat this test so that each available channel has not been connected.

6.7.3 Result

Report whether or not a fault was indicated when each channel in turn was not connected.

6.8 Load dryness

6.8.1 General

When the WD is intended to dry the load, the test specified in ISO 15883-1:2006, 6.12 shall be used and the lumen dryness test shall be carried out as described below.

6.8.2 Procedure

On completion of the process cycle remove the load (an endoscope or surrogate device) and position the endoscope so that there is a continuous fall to the lumen orifice being tested. Discharge medical grade compressed air at a pressure of 105 kPa to 120 kPa through each channel in turn with the distal end 50 mm to 100 mm above, and normal to a sheet of coloured (e.g. blue or green) crepe paper.

Tests on endoscopes shall be made on all channels with the air flow from both the umbilical side and the control valve.

Examine the paper for dampness shown by dark spots on the paper.

6.8.3 Results

Report whether or not droplets of moisture were discharged from the distal end of the endoscope/surrogate device. See 4.7.3.

6.9 Thermometric tests

6.9.1 Test for chamber and load temperature during process cycle

6.9.1.1 Test equipment

6.9.1.1.1 Temperature sensors, complying with ISO 15883-1:2006, 6.2.1 but with the overall diameter such that the temperature sensor(s) within the channels of the endoscope(s) do not reduce the flow to an extent that impairs the efficacy of the process (see 5.2.2.1).

6.9.1.2 Procedure

Locate the temperature sensors (6.9.1.1.1) as follows:

— at two diagonally opposite positions in the chamber;

— one in the approximate geometric centre of the surface of the door or lid;

— one adjacent to each automatic control temperature sensor;

— one adjacent to each process recorder temperature sensor;

— one on the control head of the endoscope in contact with a metal component;

— one in at least one channel of the endoscope at the distal end to a depth of not less than 100 mm;

— the remaining sensors on the outer surface of the insertion tube and umbilical cord of the endoscope at intervals not exceeding 750 mm.

The sensors shall be in direct physical contact with the item or installed sensor in each position being monitored and shall be placed, as far as possible, in or on the part that will be slowest to achieve the specified temperature.

Record the temperatures obtained throughout a process cycle. Perform the test in triplicate.

6.9.1.3 Results

Report the maximum deviation for each sensor from the specified temperature for each stage of the process and check for compliance with 5.4.1, 5.4.2 and 5.4.3.

6.9.2 Test for operating cycle temperature limits on washing and chemical disinfection stages

6.9.2.1 General

The test shall be applied only to those WDs in which the washing and/or disinfection stage is not thermostatically regulated.

6.9.2.2 Test equipment

Test equipment in accordance with 6.9.1.1.

6.9.2.3 Procedure

Locate the temperature sensors as described in 6.9.1.2. Run a cycle. Supply the detergent and/or disinfectant solution at a temperature 2 °C to 4 °C below the minimum temperature specified for the washing/disinfection stage. Run a second cycle. Supply the detergent and/or disinfectant solution at a temperature 2 °C to 4 °C above the minimum temperature specified for the washing/disinfection stage.

6.9.2.4 Results

Report the minimum temperature attained by the load and chamber surface during the washing and/or disinfection stage and whether or not a fault was indicated by the automatic controller.

Check for compliance with 5.4.4.

6.10 Chemical dosing tests

6.10.1 Procedure

For those WDs in which the required dose of process chemical is contained in a single-dose container which is replaced before each cycle, run cycles using a container that contains 90 % to 95 % of the intended volume.

6.10.2 Results

Report whether the automatic controller indicated a fault.

6.11 Tests of cleaning efficacy

6.11.1 General

The test procedure and test loads described below are designed to demonstrate compliance with the requirements of cleaning efficacy in accordance with ISO 15883-1:2006, 6.10 but take into consideration the complex nature of the endoscope.

The measurement of cleaning efficacy shall be made on the cleaning stage alone. This shall include any processes which take place in the WD prior to admission of the disinfectant.

Cleaning efficacy tests shall be carried out first on the surrogate device and subsequently on sufficient (but at least two) different devices to be representative of the devices that the WD is intended to process.

NOTE 1 These tests provide a basic assessment of the cleaning efficacy of the process.

NOTE 2 Attention is drawn to the inclusion of bacteria in some test soils. It may be inappropriate to use these for tests on installed, operational WDs.

For the WD manufacturer to claim that particular device(s) can be processed in the WD, data shall be required to establish that the particular device(s) can be effectively cleaned in the WD. Where an endoscope is one of a “family” of essentially similar devices it shall be sufficient to test a representative sample for the “family” of endoscopes.

NOTE 3 Where the WD manufacturer’s instructions for use with a particular endoscope requires a pre-treatment, e.g. manual cleaning of a particular component or channel, that pre-treatment can be included as part of the test procedure.

6.11.2 Load carrier

The load carrier chosen for the test load shall be of the type recommended by the WD manufacturer for the device to be processed.

6.11.3 Test loads

The type test shall be carried out using the biofilm test pieces as specified in ISO/TS 15883-5:2005, Annex F incorporated into the surrogate device as shown in Figure 2.

For operational qualification testing, a surrogate device as shown in Figure 2 or one that is representative of a specific endoscope that is intended to be processed (e.g. a stripped lumen version of the endoscope) shall be used. The test pieces in the surrogate device shall be contaminated with the test soil(s) specified in 6.11.4.

In addition, test loads composed of sufficient representative types (make, model) of device(s) that the WD is intended to process shall be used for type tests and operational testing.

NOTE To minimize the possibility of damaging an endoscope it is prudent to establish the efficacy of the process using a surrogate device before using an endoscope to verify the cleaning process.

6.11.4 Test soils

Devices to constitute a test load shall be contaminated with one or more of the appropriate test soils by the method given in ISO/TS 15883-5 for the particular test soil (for reference, see also [13] to [21]).

NOTE 1 The attention of users is drawn to local requirements that can require the use of particular test soils and methods.

NOTE 2 The attention of manufacturers is drawn to the user's choice of test soils(s) and method(s) for operational testing; this can indicate a need to carry out similar testing before the WD is supplied.

The test soils used for the load, chamber wall and load carriers may be the same or different. Where different test soils are used the rationale for the choice of test soil shall be documented.

6.11.5 Procedure

Place the test load contaminated with the test soil in the chamber. Connect the chamber to the channel irrigation devices in accordance with the WD manufacturer's instructions and process. Tests using contaminated devices shall only be carried out after satisfactory completion of the tests using the surrogate device.

Start a normal cleaning cycle for the load type under test. Interrupt the cycle just prior to the start of the disinfection stage. Then examine the test load for the presence of residual soil by the method given in ISO/TS 15883-5 for the particular test soil used.

6.11.6 Results

Report the adequacy of the cleaning process using the criteria specified for the particular test soil used in ISO/TS 15883-5.

6.12 Test of disinfection efficacy

6.12.1 General

The conditions of use of disinfectants within the WD shall be within the conditions validated and specified as acceptable by the disinfectant manufacturer.

Tests conducted on disinfectants shall be carried out at the end of the shelf life specified by the disinfectant manufacturer after the disinfectant has been stored under the worst case storage conditions specified by the disinfectant manufacturer.

NOTE Subject to national regulatory requirements, these conditions can be simulated by the use of validated accelerated ageing when necessary or, when a validated stability study is available, by diluting the disinfectant to the minimum concentration observed at the end of the shelf life specified by the disinfectant manufacturer.

Tests conducted on disinfectants produced or activated immediately prior to use shall be carried out at the minimum concentration that may be available in normal use.

National regulatory requirements can specify approval procedures for disinfectants to be used in WDs for medical devices. Compliance with these national requirements shall be deemed to meet the requirements within the territory where these requirements apply.

6.12.2 Preliminary tests on chemical disinfectants

6.12.2.1 General

An initial series of tests, as set out in 6.12.2.2 to 6.12.2.9, intended to verify, *in vitro*, the microbicidal activity of the disinfectant solution under conditions identical to those that will be applied at the time of the cycle's disinfection phase shall be carried out unless adequate data under relevant conditions can be supplied for shorter contact time(s).

For this, the virucidal, bactericidal, fungicidal, mycobactericidal and (if necessary) sporicidal activity of the disinfectant solution shall be verified.

During these tests experimental conditions intended to simulate the conditions within the WD shall be used.

These data shall be obtained from the disinfectant manufacturer, by testing carried out by or on behalf of the WD manufacturer or from a third party.

6.12.2.2 Concentration

The product shall be tested at the minimum concentration available during the disinfection phase of the cycle, based on the in-use concentration recommended by the WD manufacturer.

Each product in the list of usable disinfectants provided by the WD manufacturer shall be tested.

In the case where it is intended that a disinfectant solution be re-used, the efficacy of the solution shall be determined as a function of its minimum concentration.

6.12.2.3 Temperature

Two cases shall be considered:

— if the disinfection temperature phase is carried out under ambient conditions, the test temperature shall be the minimum temperature permitted during the cycle's disinfection phase;

— if the disinfection phase is carried out under temperature controlled conditions, the test temperature shall correspond to the disinfection temperature specified by the WD manufacturer.

6.12.2.4 Contact time

Two cases shall be considered:

— if the disinfection phase is carried out under ambient conditions, the contact time observed during the tests shall be equal to the minimum duration of the disinfection phase;

— if the disinfection phase is carried out under temperature controlled conditions, the contact time observed during the tests shall be equal to the minimum duration of the disinfection phase during which the temperature of the disinfectant solution is constantly at, or above, the minimum specified temperature.

The above applies unless adequate data under relevant conditions can be supplied for shorter contact time(s).

6.12.2.5 Water quality

If the efficacy of the disinfectant is liable to be impaired by dilution with hard water then testing shall be carried out with a disinfectant solution prepared by dilution with water of hardness in accordance with 6.4.2.

6.12.2.6 Neutralization

Before commencing an investigation of the efficacy of the disinfectant a method of neutralizing the disinfectant at the end of the exposure period shall be demonstrated and documented. This shall include demonstration that, for any neutralizing agent used, neither the neutralizing agent nor its reaction product with the disinfectant are microbicidal or bacteriostatic. When a secondary host, such as a cell culture, is used as the detection system for the survival of test organisms, the absence of carry over effects on the cell culture system and detection of low numbers of test organisms added as a challenge to the test system shall be demonstrated.

6.12.2.7 Test organisms

Test organisms shall be selected on the basis of the following criteria:

— documented high resistance to the disinfectant under investigation;

— species typically found on item to be processed;

— species of clinical significance that may be found on item to be processed;

— representative species of a major group of organisms, e.g. Gram positive bacteria.

As a minimum, the test organisms shall include Gram positive and Gram negative vegetative bacteria, bacterial spores, mycobacteria, non-lipid viruses, lipid viruses and fungi (including spore forms and yeasts).

NOTE Guidance on choice of organisms may be obtained from relevant published standards on disinfectant efficacy testing e.g. EN 13624, EN 13727, EN 14348, EN 14476.

6.12.2.8 Presentation of test organisms

While initial potency tests may be carried out using a suspension of test organisms, the demonstration of activity on contaminated surfaces shall be required. The surfaces of the test pieces to be inoculated with test organisms shall be representative of those found in the WD chamber and the devices to be processed. See 6.12.2.7.

6.12.2.9 Detection of test organisms

The culture method used to enumerate the number of surviving microorganisms after exposure to the disinfectant shall be validated. The culture method shall be capable of recovering a low number (approximately ten) of the organisms for which it is intended to be used.

6.12.3 Self-disinfection tests

6.12.3.1 Type test

The type test is intended to verify that the WD “self-disinfection” mode will disinfect those parts of the WD which come into contact with fluids that are intended to, or may, contact the load.

NOTE The WD may be equipped with an automatic or manually selected “self-disinfection” mode. It may be thermal or chemical. In the latter case it may be the same or a different disinfectant from that used for chemical disinfection of the load. The preferred method is thermal disinfection.

The test method described in ISO/TS 15883-5:2005, Annex F shall be used.

6.12.3.2 Operational and routine test

The test on the final rinse water shall be sufficient to verify the self-disinfection cycle. (see 6.3). The sample shall be taken from any suitable point that ensures that water is collected which has circulated through the components that were to be disinfected.

6.12.4 Test of microbial quality of final rinse water treatment equipment

6.12.4.1 Type test

The efficacy of the treatment system shall be challenged by inoculation with the test organism *E coli* K12 upstream of the treatment system. The inoculum shall be sufficient to produce a population of 10^6 organisms per millilitre in the final rinse water if there was no effect from the treatment system. A sample of the final rinse water (not less than 200 ml) shall be collected during an operating cycle. Analyse two 100 ml aliquots for the number of remaining organisms by the filtration method.

Report the number of colony forming units recovered from each of the two tests.

There shall be less than 10 cfu recovered from each of two 100 ml aliquots tested.

6.12.4.2 Operational tests

Various treatment methods are used to ensure that the water from water treatment equipment is of appropriate microbial quality before use.

The test shall verify the performance of the particular system by the method specified by the manufacturer.

This shall include, as necessary:

— verification of filter performance by an integrity test (e.g. bubble point test);

— verification of thermal disinfection by thermometric testing.

6.12.5 Disinfection of liquid transport systems following failure of water treatment equipment

6.12.5.1 Type test

The test methods specified in D.5.2.1 and D.5.2.2 shall be used to evaluate the disinfection of the water treatment equipment.

6.12.5.2 Operational and routine test

The test on the final rinse water as specified in 6.3 and Annex E shall be sufficient to verify the self-disinfection cycle. The sample shall be taken from any suitable point that ensures that water is collected that has circulated through the components that were to be disinfected.

6.12.6 Chemical disinfection of the load

6.12.6.1 Type test

The test shall be carried out in accordance with Annex B.

The test method shall use a surrogate device to simulate the load items and inoculated carriers shall be incorporated as part of the surrogate device to monitor the efficacy of the disinfection stage. A range of microorganisms shall be used.

NOTE 1 A range of organisms is suggested but others can be used at the discretion of the microbiologist, or at the request of the user.

NOTE 2 For further information on microbial testing of chemical disinfection processes, see Annex G.

6.12.6.2 Operational tests

Operational tests shall establish that the levels of all controlling variables that affect the disinfection of the load are within the limits established during type testing.

6.12.6.3 Performance qualification and routine test

When required by national regulation, a surrogate device shall be used to simulate the load items. Inoculated carriers shall be incorporated as part of the surrogate device to monitor the efficacy of the disinfection process.

NOTE 1 Microorganisms incorporated into test soils may be used instead of, or as well as, the use of inoculated carriers (see ISO/TS 15883-5).

For performance qualification and routine tests the process shall be verified by sampling endoscopes that have been used on patients after processing. The post-disinfection microbial contamination shall be estimated by analysis of samples taken immediately after the post-disinfection rinsing stage. Sufficient samples for each test shall be used to provide assurance of elimination of microbial contamination i.e. there shall be no recovery of microorganisms from the processed endoscopes samples.

NOTE 2 Guidance on a suitable sampling protocol may be seen in [23] and [24]

7 Documentation and inspection

Documentation and inspection shall be in accordance with ISO 15883-1:2006, Clause 7.

8 Information to be supplied by the manufacturer

In addition to the information specified in ISO 15883-1:2006, Clause 8 the WD manufacturer shall provide the following information:

a) the devices and/or device families for which the WD manufacturer has evidence that they can be processed satisfactorily and any precautions necessary for particular devices or operational conditions (e.g. see 4.1.4 and 5.2.2.1);

b) for each device and/or device family, description of the number and type of connections required for channel irrigation;

c) the minimum and maximum flow and the maximum pressure of fluids which may be delivered to each channel during processing in the WD (see 5.2.1.3);

d) the maximum permissible restriction of flow through each channel before the automatic controller will indicate a fault (see 5.2.2.1);

e) the maximum temperature of any process fluid that may be in contact with the device during processing in the WD and which may cause degradation of the device;

f) the maximum temperature variation permissible during the automatic leak test (if fitted);

g) details of which parts of the WD are subjected to disinfection during the self-disinfection cycle (see 4.8.3);

h) guidance on the frequency at which any water treatment equipment that is part of the WD should be disinfected (see 4.9.2.1);

i) diagram of the circulation of fluids in the WD used to irrigate channels in the device (see 5.2.1.2);

j) instructions for use including:

   — the recommendation to use thermal disinfection for heat stable devices and accessories (see 4.1.8);

   — guidance on the need for drying devices which are to be stored before use (see 4.7.1);

   — means to verify the flow of process fluids through each channel (see 5.2.1.1);

   — the method and frequency for disinfection of the connection between the WD and the water supply for post-disinfection rinse water (see 4.9.2.3);

   — the method to be used for collecting samples of final rinse water from the chamber;

   — for WDs not provided with an automatic leak test, the information that a manual leak test is required prior to processing [see 4.2.2 b)];

k) locations of temperature sensors being representative of the lowest temperatures on the systems (see 4.8.6);

l) maintenance instructions, including the planned preventive maintenance required on the piping used to convey post-disinfection rinse water to the endoscope and the frequency at which such piping should be replaced (see 4.9.3);

m) the detergent(s) and disinfectant(s) to be used with the WD (as established during type testing), (see 4.3.3 and 4.4.5);

n) if the water treatment equipment is not part of the WD, the requirements for water supplied to the WD including the requirement to control the microbial contamination of the water supply (see 4.9.2.2);

o) quality of the rinse water used for post-washing rinsing (see 4.3.4);

p) details on how, or to which port on the WD, the endoscope channels are to be connected (see 5.2.1.2).

9 Marking, labelling and packaging

Marking, labelling and packaging shall be in accordance with ISO 15883-1:2006, Clause 9.

10 Information to be requested from the purchaser by the manufacturer

The requirements of ISO 15883-1:2006, Clause 10 apply.

In addition, the following information shall be requested from the user:

a) the means that shall be provided to ensure that connection is made to the correct container of process chemical see (4.1.7);

b) list of all types of endoscopes and devices that the user intends to process in the WD.

Annex A
(informative)

Summary of activities covered by this Part of ISO 15883

A.1 General

This part of ISO 15883 covers a range of activities. The responsibilities for discharging these activities are not addressed within this part of ISO 15883. This annex is intended to give guidance on an appropriate division of responsibility for these activities.

The key personnel are:

— the WD manufacturer;

— the medical device (endoscope) manufacturer;

— the process chemical manufacturer (detergents, disinfectants);

— the purchaser/user.

A.2 Before installation of the WD

The overall responsibility for the design and construction of the WD is necessarily with the WD manufacturer. This part of ISO 15883 also requires the WD manufacturer to:

— state with which endoscopes the WD can be used; this is to be done in the light of information provided by the endoscope manufacturer;

— provide test data demonstrating the performance of the WD with respect to both cleaning and disinfection using process chemicals specified by the WD manufacturer; this is to be done in the light of information provided by the process chemical manufacturer;

— seek information from the user on the quality of water available on the site where the WD is to be installed;

— carry out type testing on each model of WD to establish compliance with the requirements of this part of ISO 15883;

— carry out works testing to establish that each WD released to the market is functioning to the standard established by type testing;

— provide information to the user to support the correct use of the WD (including, where necessary, reference to the endoscope manufacturer's instructions for reprocessing).

A.3 Installation and operation of the WD

Once the WD is installed on site the overall responsibility for ensuring that the WD is correctly installed and functions correctly would usually fall to the purchaser/user. This would include:

— installation checks and tests;

— operational tests;

— performance qualification tests;

— periodic tests;

— use of the recommended process chemicals;

— operation of the WD in accordance with the WD manufacturer's instructions (including limiting the devices reprocessed through the WD to those which the WD manufacturer has specified).

Annex B
(normative)

Microbiological testing of the efficacy of chemical disinfection of the load

B.1 Test organisms

B.1.1 A range of organisms representing the major groups and showing high resistance to the disinfectant shall be used (see 6.12.2.7).

NOTE The organisms listed below are suggested as suitable. (These are, for example, the organisms specified in EN 13624, EN 13727, EN 14348, EN 14476.) Additional organisms, or alternate organisms, that demonstrate high resistance to the disinfectant under the intended conditions of use (temperature, concentration etc.), or that are relevant for a particular application, may be used.

Preferred species are:

Pseudomonas aeruginosa (e.g. ATCC 15442)

Serratia marcescens (e.g. ATCC 13880)

Staphylococcus aureus (e.g. ATCC 6538)

Enterococcus faecium (e.g. ATCC 12952)

Enterococcus hirae (e.g. ATCC 10541)

Mycobacterium terrae (e.g. ATCC 15755)

Mycobacterium avium (e.g. ATCC 15769)

Candida albicans (e.g. ATCC 10231)

Aspergillus (spores) niger (e.g. ATCC 10864)

Adenovirus type 5 Adenoid 75 (e.g. ATCC VR-5)

Poliovirus Type 1 LCs-2ab a

Bovine parvovirus strain Haden (e.g. ATCC VR-767)

spores of Geobacillus stearothermophilus (e.g. ATCC 7953)

spores of Bacillus subtilis/atropheus (e.g. ATCC 6633)

B.1.2 Defined strains from a type culture collection shall be used.

B.1.3 The test shall be carried out either with a range of organisms (see examples given in B.1.1) identified as most resistant to the particular disinfectant in preliminary tests (see 6.12.2.7), or such other organisms as have been determined to have particular resistance to the disinfection process or to be particularly relevant to the intended application. Tests should include challenges with one or more virus strains, a strain of mycobacteria and bacterial spores.

NOTE 1 The test methods described below are not applicable to tests with viral strains. Guidance on appropriate test methods for viral strains may be found in e.g. EN 14476.

NOTE 2 Elimination of bacterial spores is not expected from a disinfection process, however some sporicidal activity is expected (see Note to 4.4.2.5). The low level of activity against spores compared with vegetative cells makes the spores a useful indicator of the extent of removal compared with kill. The use of a thermophilic spore facilitates recovery without interference from mesophilic microorganisms which are also present.

B.2 Preparation of inoculum

B.2.1 Culture conditions

B.2.1.1 General

Details of the methods of preparation of cultures shall be reported with the results. Wherever possible standard published methods shall be used.

B.2.1.2 Suspending menstruum

Bacterial spores shall be suspended in sterile distilled water.

The other test organisms shall be suspended in a suitable sterile isotonic solution, e.g. for bacteria, peptone water with 10 % sodium glutamate.

B.2.1.3 Inoculum

The inoculum shall contain known high numbers of the test organism, e.g. for bacteria the inoculum shall contain not less than 10^8 cfu/ml. The population in the original inoculum and deposited on the test piece for exposure to the disinfection process shall be counted using a validated method.

B.3 Test pieces

A surrogate device for investigation of cleaning and disinfection should be used (see 6.6.2).

Test pieces for inoculation may be formed from 150 mm lengths of the same diameters of PTFE tubing.

These may then be positioned at each end and in the middle of the long lengths of tubing. They should be held in position with a sleeve made from a short length of silicone rubber tube of greater diameter. The overall length of each tube, including the three test pieces, should be not less than 1,5 m.

B.4 Inoculation method

Use a microsyringe to dispense 25 µl aliquots into each of the 150 mm long test pieces. Rotate these test pieces until visibly dry and repeat the procedure three more times.

B.5 Recovery method

Transfer the inoculated test piece to a sterile isotonic solution containing a suitable neutralizer for the disinfectant.

Remove the inoculated test piece after the validated exposure time to the neutralizer.

Cut the 150 mm length of inoculated test piece in half and cut then one of the halves in half again and then slit lengthwise with a sterile scalpel. Transfer the split halves to 20 ml of sterile ¼ strength Ringers solution containing 0,05 % polysorbate 80 in a thin walled glass screw capped container (e.g. 25 ml universal bottle).

Transfer the container to an ultrasonic bath and ultrasonicate for 10 min at 45 KHz.

Use the eluate to prepare a dilution series from which a viable count shall be determined.

Transfer the other half of the test piece to recovery medium (growth/no growth test).

B.6 Procedure

B.6.1 Evaluation of initial inoculum

Test the test pieces prepared as described above by the recovery method to establish the population of each test organism which can be recovered from the inoculum.

B.6.2 Evaluation of physical removal using spores as an indicator organism

Expose the surrogate devices incorporating test pieces inoculated with *Geobacillus stearothermophilus* spores to the disinfection stage, run with water instead of disinfectant solution, and recover by the method described. The difference in population between the two test pieces and the original inoculum is a measure of the extent to which test organisms are physically removed by the WD disinfection stage.

NOTE Thermophilic spores are used during type testing in order to ensure that any spores remaining in the WD do not interfere with subsequent tests employing mesophilic organisms.

There shall be not less than 10^5 spores remaining on each of the test pieces exposed to the simulated WD disinfection stage.

If there is significant sporicidal activity from the disinfectant it will be necessary to evaluate the physical removal of test organisms by repeating the study with *Geobacillus stearothermophilus* spores with the disinfectant solution replaced by water.

When it can be established that the disinfectant formulation does not include surfactant and/or detergent activity the test may be carried out using vegetative organisms e.g. *Enterococcus faecium* and replacing the disinfectant solution with water.

For some WDs it may be necessary to reduce the rate and/or volume of flow through the surrogate device during this test in order to ensure that at least 10^5 spores remain. When this is done it should be clearly indicated on the type test report.

B.6.3 Evaluation of disinfection efficacy

Expose the surrogate devices incorporating test pieces inoculated with test organism to the WD disinfection stage and recover by the method described. Carry out all tests in duplicate.

B.7 Results

Report the $\log_{10}$ reduction obtained for each test organism used (see 4.4.2.4).

Annex C
(informative)

Summary of test programmes

Table C.1 — Summary of tests in addition to ISO 15883-1:2006

Brief description of test	Subclause		Nature of test				
	Requirement	Test	Type	Works	Operational	Performance	Routine
1. Leak test failure alarm	4.2.3	6.5	X	X	X	B	X (Q)
2. Leak test	4.2.5	6.5	X	X	X	B	X (Q)
3. Cleaning efficacy	4.3.5	6.11	X	B	X	X	X (Q)
4. *In vitro* disinfectant efficacy	4.4.2	6.12.2	X	B	B	B	B
5. Disinfection efficacy – Type test	4.4.1	6.12.6.1	X	B	B	B	B
6. Disinfection efficacy – Operational and performance tests	4.4.2	6.12.6.2	O	B	X	X	X (Q)
7. Temperature of disinfection stage (see 17 below)	4.4.3	6.9	x	O	O	X	X (Q)
8. Drying	4.7	6.8	X	O	X	B	B
9. Disinfection of liquid transport system – Type test	4.8.5	6.12.5.1	X	B	B	B	B
10. Disinfection of liquid transport system – Operational and routine	4.8.5	6.12.5.2	O	B	X	B	X
11. Self-disinfection test – Type	4.8.7	6.12.3.1	X	B	B	B	B
12. Self-disinfection test – Operational and routine	4.8.7	6.12.3.2	O	B	X	B	X
13. Disinfection of water treatment equipment	4.9.2	6.12.4	X	B	O	B	B
14. Final rinse water treatment – Microbial quality	4.5.2	6.12.4	X	B	X	B	B
15. Channels non-obstruction test	5.2.2.1	6.6	X	X	X	B	X (Q)
16. Channels not connected test	5.2.2.2	6.7	X	X	B	X	X (Q)
17. Temperature throughout process	5.4.2 5.4.3	6.9.1	X	X	X	X	X (Q)
18. Minimum process temperature test	5.4.4	6.9.2	X	X	X	X	X (Q)
19. Water quality	4.5.2 4.9.2.2 a 4.9.2.2 b	6.3	B	B	X	X	– X (W) X (Q)
20. Chemical dosing test (single-dose container)	5.7	6.10	X	X	X	B	O
21. Leak test non-connection test	4.2.4 4.2.5	6.5.3.4	X	X	B	X	B

X – Recommended, B – Not recommended, O – Optional.

Frequencies: Q – Quarterly, W – Weekly.

Annex D
(normative)

Methods for microbiological evaluation of disinfection of liquid transport system

D.1 General

The following two methods are intended to simulate various incidents that might arise during normal use of the WD, and that could give rise to contamination of the WD (see 4.9.2 and 6.12.5).

Method 1 (specified in D.5.2.1) tests the self-disinfection cycle after a simulated water treatment equipment malfunction that, although repaired quickly (24 h later), has caused contamination of the WD by the microorganisms present in the supply water.

Method 2 (specified in D.5.2.2) also simulates the case of WD contamination by microorganisms present in the supply water following a malfunction of the internal water treatment equipment. However, in this case, the self-disinfection cycle is only applied one week after a water equipment malfunction, and that during this week the WD has continued to be used (one endoscope washing/disinfection cycle per day). This allows evaluation of the efficiency of the self-disinfection cycle of a potentially contaminated WD after one week of use. Moreover, monitoring the internal level of contamination of the WD during the interval of time between the water treatment equipment failure and the execution of the self-disinfection cycle will allow evaluation of whether the WD's design is effective in limiting the development of microorganisms in the pipes of the WD.

D.2 Apparatus and reagents

D.2.1 Endoscope WD.

D.2.2 *Pseudomonas aeruginosa* CIP A22 (or equivalent) as microorganism.

D.2.3 Bacterial suspension, with 1×10^9 cfu/ml to 1×10^{10} cfu/ml in sterile distilled water.

D.2.4 Soybean casein digest (SCD) agar, as maintenance and counting medium (see EN 12353).

D.3 Cycles

D.3.1 General

The following cycles shall be available:

— endoscope WD cycle;

— self-disinfection cycle;

— sampling cycle;

— contamination cycle.

D.3.2 Sampling cycle

The sampling cycle shall correspond to a routine endoscope cleaning and disinfection cycle interrupted during the stage before disinfection, and for which the detergent shall be replaced by sterile distilled water. Once the cycle has been interrupted, a sample from the bottom of the tank containing water having circulated in the WD's pipe work shall be taken.

NOTE This sampling programme only includes the cleaning and rinsing phase and circulates water throughout the WD's pipe work, without there being any addition of disinfectant or detergent product.

If the cycle cannot be interrupted immediately prior to the disinfection stage then a complete cycle substituting sterile purified (e.g. reverse osmoses) water for all process chemical solutions shall be used.

D.3.3 Contamination cycle

This special programme corresponds to a routine cleaning and disinfection cycle for which:

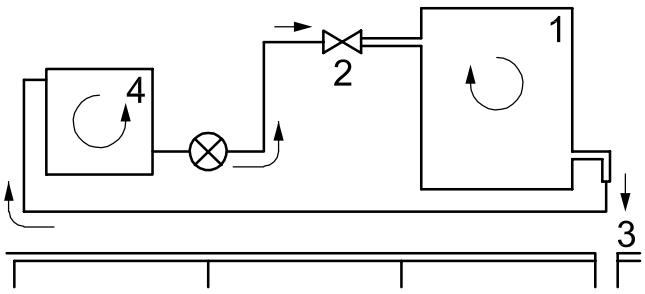
— the disinfectant solution heating system (if fitted) is deactivated;

— the detergent and disinfectant are replaced by sterile distilled water.

During this contamination cycle, the WD is connected to the external tank containing the contamination solution (see Figure D.1), so that during each phase of the contamination cycle, the WD is only fed with the contamination solution contained in the external tank.

D.4 Connection of the WD to the external tank

The connection of the WD to the external tank shall be as shown in Figure D.1.



Key

1 WD
2 water supply
3 drainage
4 external tank

NOTE As a function of manufacturer's recommendations, external peripherals can be inserted between the water supply network and the WD (water softener, etc).

Figure D.1 — Connection of the WD to the external tank — Test configuration

D.5 Procedure

D.5.1 General

D.5.1.1 External tank disinfection

Before each test, subject the external tank in which the contamination solution is prepared to a thermal disinfection cycle with an A_0 of not less than 600.

D.5.1.2 Verification of absence of microbiocidal residue in the external tank after disinfection

During the last rinsing stage of the external tank, collect 9 ml of the water circulating in the external tank and associated pipework.

Incorporate 1 ml of a bacterial suspension of *Pseudomonas aeruginosa* at 10^3 bacteria/ml in the previously-sampled 9 ml of water.

After mixing thoroughly and 10 min of contact time, establish the number of viable bacteria present in the reaction mixture, T_N, by serial dilution and counting on an SCD agar plate.

The rinsing is only considered to be valid if

$$10 \times \frac{T_N}{T_t} \geqslant 0{,}8 \qquad \text{(D.1)}$$

where

T_N is the number of viable bacteria present in the reaction mixture;

T_t is the exact concentration of bacteria in the bacterial suspension (control).

D.5.1.3 Preparation of the contamination solution

Fill the external tank with 30 l of tap water and 30 ml of a *Pseudomonas aeruginosa* suspension containing 10^9 cfu/ml. After thorough mixing, take a sample in order to establish, by serial dilution and counting on a SCD agar plate, the exact concentration of microorganisms in the contamination solution, T_c.

D.5.1.4 Contamination of the WD via the water supply network

After having prepared the contamination solution and deactivated the WD water treatment unit, connect the WD subjected to the tests to the external tank (Figure D.1). Then start the WD contamination cycle in order to ensure circulation of the contamination solution in all the internal piping of the WD.

D.5.1.5 Determination of the WD contamination level

During the different tests, determine the contamination level of the WD by running a sampling cycle and then establishing the concentration of microorganisms in the water having circulated in all the piping of the WD during this cycle. For this, during the sampling cycle collect 2 l of water in the tank of the WD. Filter 10 ml, 100 ml and 1 000 ml of the 2 l of water through 0,2 µm membranes. Then rinse the membranes with 3×50 ml of sterile distilled water, place on counting medium and incubate at 37 °C for 24 h.

After incubation, count and identify the number of colony forming units, and express the results as a number of colony forming units per litre.

D.5.2 Establishment of the efficacy of the disinfection of the liquid transport system

D.5.2.1 Method 1

Proceed as follows:

1) install the WD;
2) run a self-disinfection cycle;
3) run a sampling cycle;
4) determine the WD contamination level;
5) deactivate the water treatment system (i.e. remove filter, deactivate heating system);
6) disinfect the external tank;
7) prepare the contamination solution;
8) contaminate the WD via the water supply network;
9) leave the WD at room temperature (not less than 20 °C) to incubate for 24 h;
10) connect the WD normally;
11) re-activate the water treatment system;
12) run a self-disinfection cycle;
13) run a sampling cycle;
14) determine the contamination level of the WD in accordance with D.5.1.5;
15) if the analysis of the results shows more than 10 cfu/100 ml in the sample taken during step 14), repeat steps 12), 13) and 14) until reduction of the contamination to not more than 10 cfu/100 ml;
16) report the number of self disinfection cycles needed to reduce the contamination to not more than 10 cfu/100 ml.

NOTE It is not necessary to determine the contamination level before the disinfection cycle (step 12 above) since the extent of contamination that will occur is specific to the design of the WD liquid transport system. Carrying out such sampling may also remove significant microbial contamination from the system.

D.5.2.2 Method 2

Proceed as follows:

1) install the WD;
2) run a self-disinfection cycle;
3) run a sampling cycle;
4) determine the contamination level of the WD;
5) deactivate the water treatment system;
6) disinfect the external tank;
7) prepare the contamination solution;

8) contaminate the WD via the water supply network;

9) leave the WD at room temperature (not less than 20 °C) to incubate for 48 h;

10) connect the WD normally;

11) re-activate the water treatment system;

12) run a standard endoscope cleaning and disinfection cycle;

13) run a sampling cycle;

14) determine the contamination level of the WD in accordance with D.5.1.5;

15) leave the WD at room temperature (not less than 20 °C) to incubate for 24 h;

16) run a standard endoscope washing-disinfection cycle;

17) run a sampling cycle;

18) determine the contamination level of the WD in accordance with D.5.1.5;

19) leave the WD at room temperature (not less than 20 °C) to incubate for 24 h;

20) run a standard endoscope washing-disinfection cycle;

21) run a sampling cycle;

22) determine the contamination level of the WD in accordance with D.5.1.5;

23) leave the WD at room temperature (not less than 20 °C) to incubate for 24 h;

24) run a standard endoscope washing-disinfection cycle;

25) run a sampling cycle;

26) determine the contamination level of the WD in accordance with D.5.1.5;

27) leave the WD at room temperature (not less than 20 °C) to incubate for 24 h;

28) run a standard endoscope washing-disinfection cycle;

29) run a sampling cycle;

30) determine the contamination level of WD in accordance with D.5.1.5;

31) leave the WD at room temperature (not less than 20 °C) to incubate for 48 h;

32) run a self-disinfection cycle;

33) run a sampling cycle;

34) determine the contamination level of the WD in accordance with D.5.1.5;

35) if the analysis of the results shows the presence of more than 10 cfu/100 ml in the sample taken during step 33), repeat steps 32), 33) and 34) until reduction of the contamination to not more than 10 cfu/100 ml;

36) report the number of self disinfection cycles needed to reduce the contamination to not more than 10 cfu/100 ml.

Annex E
(normative)

Tests for microbial contamination of post-disinfection rinse water

E.1 Water samples

Take samples from draw-off points adjacent to the WD and from the point of discharge into the WD chamber or load, and label “Supply Sample” and “WD Sample” respectively.

Sampling containers shall be 250 ml, or larger, and shall be sterile.

Test the samples within 4 h of collection or store at 2 °C to 5 °C and test within 48 h of collection.

Swab the discharge surfaces of the sampling points thoroughly with 0,2 µm filtered 70 % iso-propanol and allow to dry by evaporation immediately before the sample is taken.

Collect a sample of not less than 200 ml, or as specified, from each sampling point for each test to be carried out.

E.2 Test for aerobic mesophilic bacteria

Test post-disinfection rinse water for aerobic mesophilic bacteria in accordance with ISO 15883-1:2006, 6.4.2.4 and Annex C.

E.3 Test for environmental mycobacteria

Filter a 100 ml aliquot of the sample under vacuum through a 0,45 µm filter that is of appropriate size to allow its transfer and incubation as described below (e.g. 47 mm diameter).

Transfer the filter aseptically to the surface of a Middlebrook[2)] 7H10 Agar plate and incubate at (30 ± 2) °C. The plates should be read regularly. Incubation should be continued for 28 d before it is concluded that no growth has occurred.

The petri dish should be sealed to prevent dehydration of the growth medium.

Carry out the test in duplicate. Examine the filters weekly and count and record the number of colonies of bacterial growth.

Report the mean number of colony forming units per sample.

NOTE If plates are overgrown by relatively faster growing contaminants within 48 h to 72 h, it may be necessary to resample and perform a preliminary partial decontamination of the sample with one or more chemicals to which mycobacteria are more resistant than the other organisms.

If growth of mycobacteria is observed consideration should be given to having the cultures transferred to a specialist laboratory for identification of the *mycobacterial* strains isolated.

E.4 Test for legionellae

Test post-disinfection rinse water for *legionelle* in accordance with ISO 11731-2.

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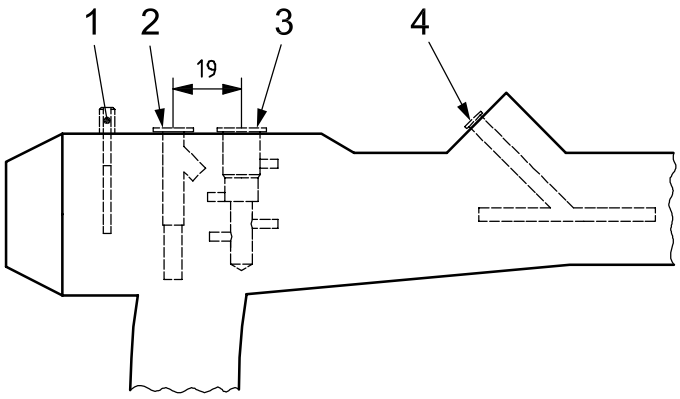
2) Middlebrook is a trade name. This information is given for the convenience of users of this part of ISO 15583 and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same results.

Annex F
(informative)

Typical specifications of trumpet valves and connection ports

Dimensions in millimetres



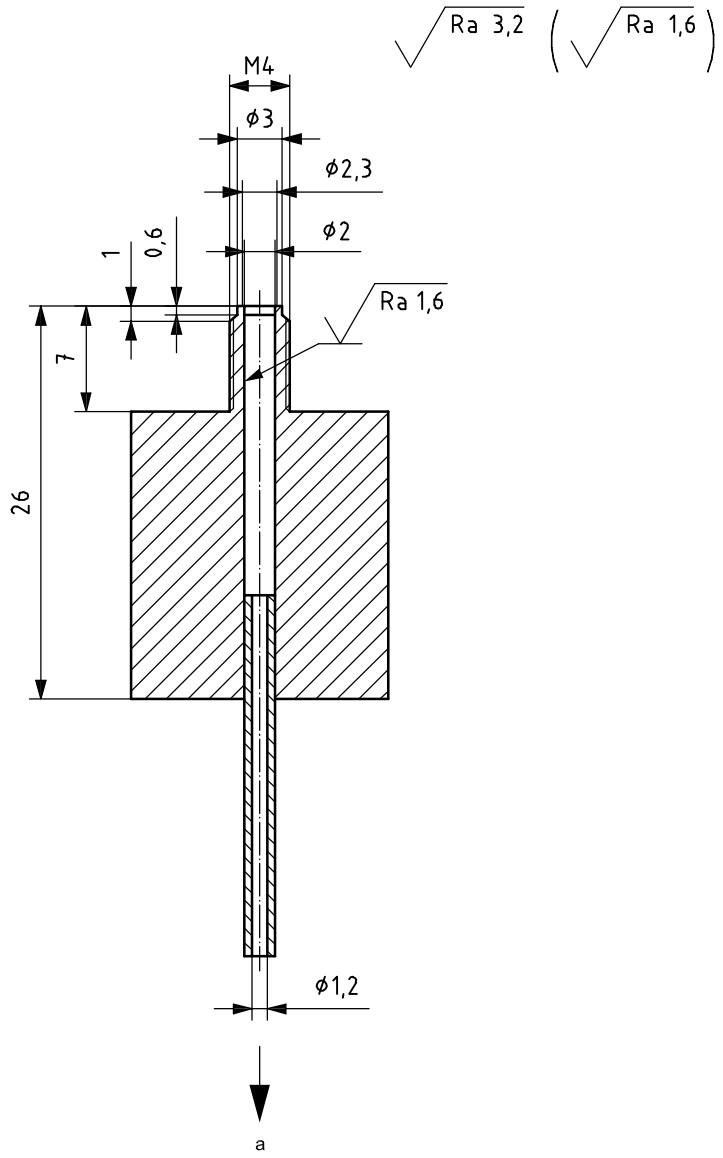
Key

1 elevator channel access port
2 suction valve
3 air/water valve
4 biopsy port

NOTE Tolerances should be $^{+0,1}_{0}$ mm for holes, $^{0}_{-0,1}$ mm for shafts and ± 0,1 mm for others.

Figure F.1 — Overview of the control body — Position of valves and ports

Dimensions in millimetres

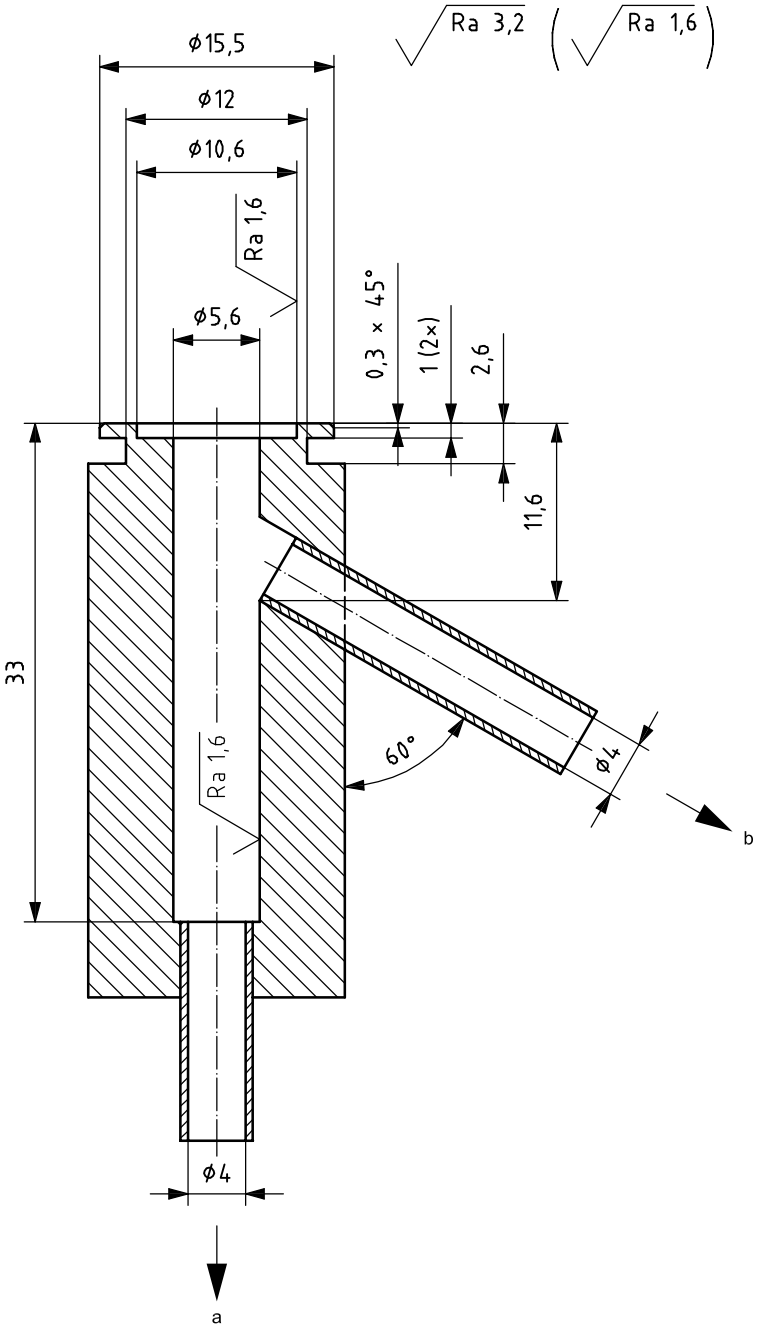


[a] To distal end.

NOTE Tolerances should be $^{+0,1}_{0}$ mm for holes, $^{0}_{-0,1}$ mm for shafts and ± 0,1 mm for others.

Figure F.2 — Example of an elevator channel access port

Dimensions in millimetres



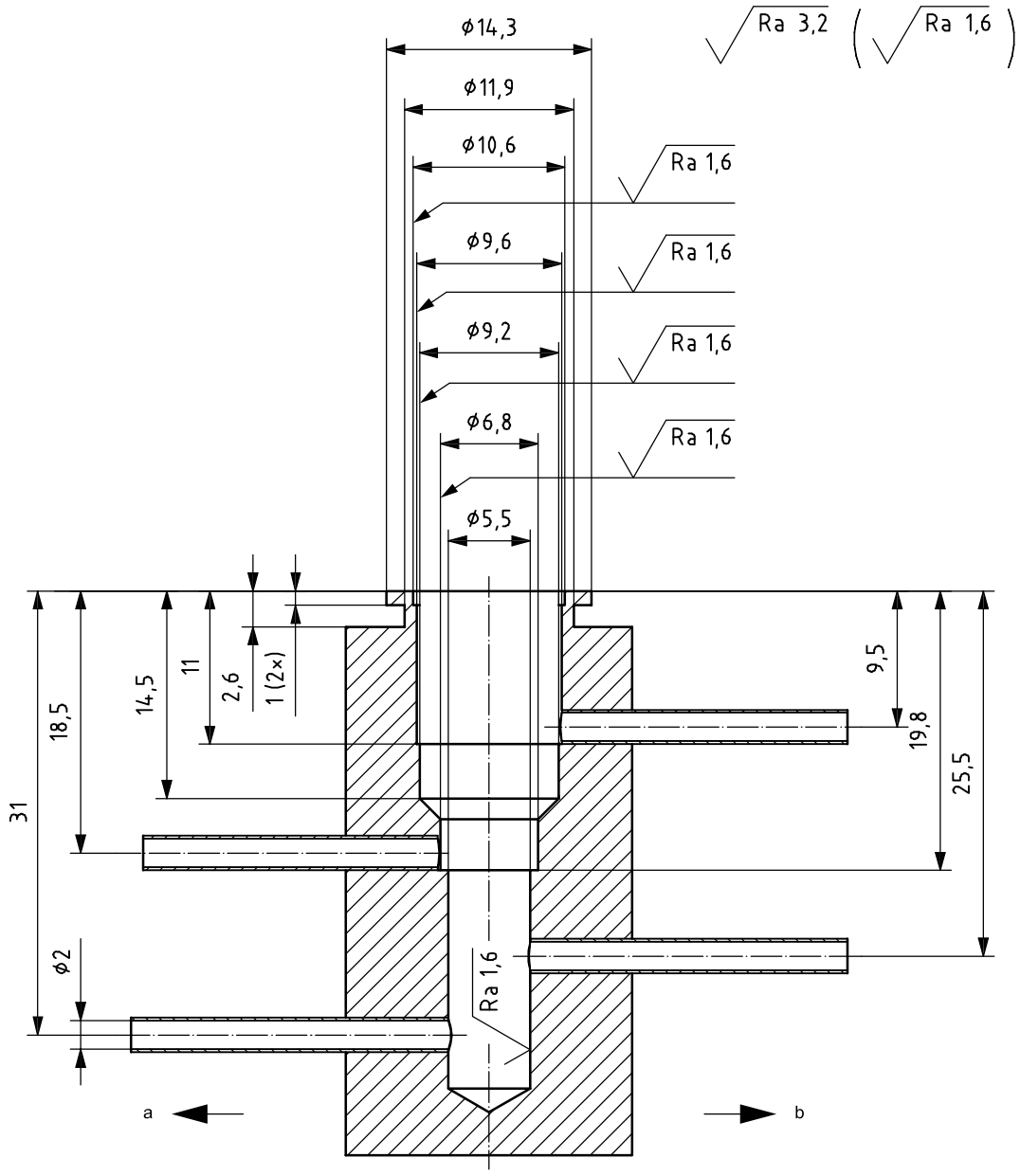
a To light/video connector.

b To biopsy port.

NOTE Tolerances should be $^{+0,1}_{0}$ mm for holes, $^{0}_{-0,1}$ mm for shafts and ± 0,1 mm for others.

Figure F.3 — Example of a suction valve

Dimensions in millimetres



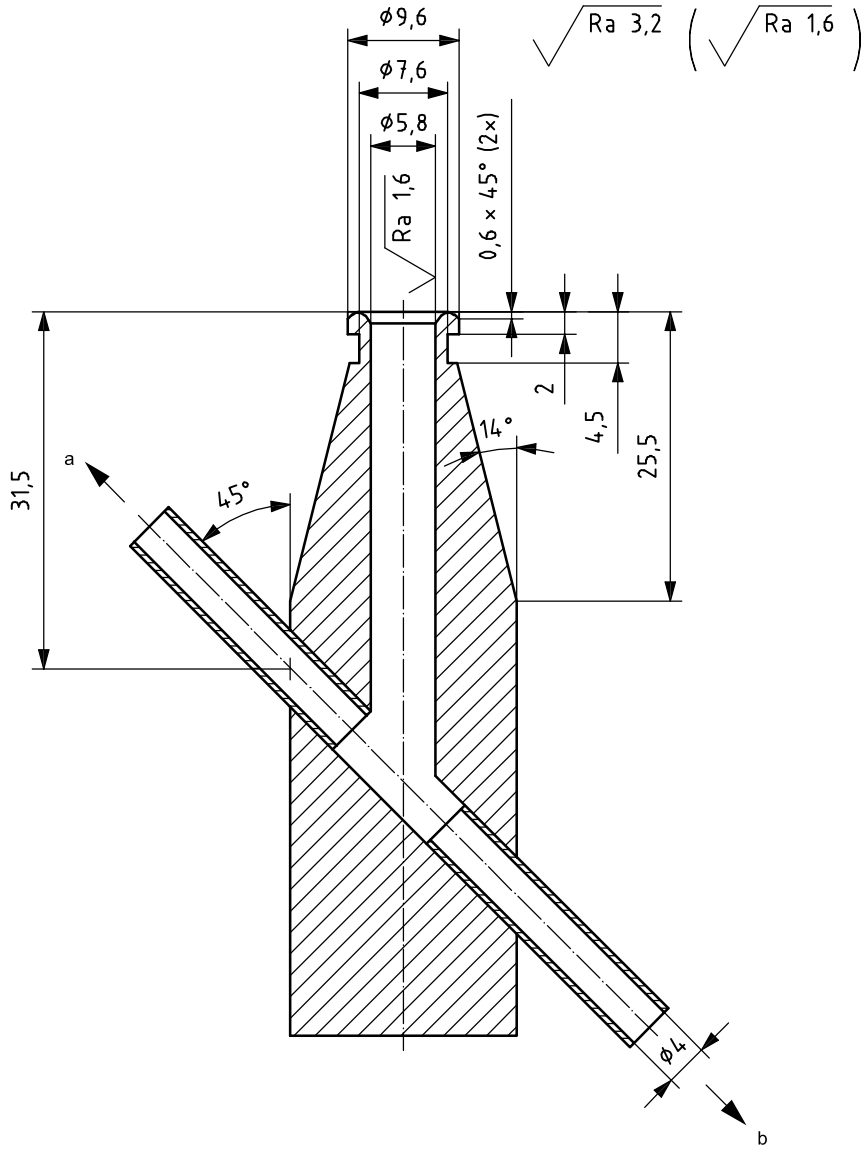
[a] To light/video connector.

[b] To distal end.

NOTE Tolerances should be $^{+0,1}_{0}$ mm for holes, $^{0}_{-0,1}$ mm for shafts and ± 0,1 mm for others.

Figure F.4 — Example of an air/water valve

Dimensions in millimetres



a To suction valve.

b To distal end.

NOTE Tolerances should be $^{+0,1}_{0}$ mm for holes, $^{0}_{-0,1}$ mm for shafts and ± 0,1 mm for others.

Figure F.5 — Example of a biopsy port

Annex G
(informative)

Additional notes on microbiological testing of chemical disinfection processes

G.1 Difficulties with microbial testing

There are a number of difficulties associated with microbiological monitoring of the disinfection process in a WD. These include, but are not limited to, the following.

a) The end-point which is desired in practise (no survivors) does not allow quantitative interpretation of the results and does not provide assurance that the recovery method used would detect surviving organisms.

b) Artificial inoculation of surfaces to be disinfected may not adequately simulate the naturally occurring microflora because both the resistance of the organisms and the adhesion of the organisms to the surface may be changed by *in-vitro* culture and preparative methods (harvesting, cleaning, inoculation etc.).

c) "Worst-case" conditions may be created by the use of high numbers which are also necessary to give quantifiable results. However, these may not be representative of naturally occurring populations due to clumping etc.

d) The addition of organic material (usually serum or blood) and/or inorganic material (usually the mineral salts causing hardness of water) may be used to simulate soiling but there are few data to support the correlation of these artificial soils with naturally occurring soiling.

e) The organisms which are normally of interest are pathogens (both obligate and facultative or opportunistic) but the use of non-pathogenic strains is necessary for test purposes. In many cases the evidence correlating the behaviour and resistance of the different species and strains is scant or absent.

f) The surfaces of particular interest are frequently the internal surfaces of devices with long narrow lumens. Their inaccessibility makes quantative inoculation and recovery more difficult.

G.2 Verification of the disinfection process

During normal processing the cleaning and rinsing stages of a WD cycle are designed to remove surface soiling and should therefore remove most of the contaminating microorganisms.

In carrying out tests to verify the efficacy of the chemical disinfection process it is therefore necessary either:

a) to evaluate the removal of microorganisms which occurs during the cleaning and rinsing stages and demonstrate that this removal efficacy is reproducible within acceptable limits (i. e. such that for a known initial contaminating population there will be a known residual population present at the start of the disinfection stage)

or

b) to eliminate the cleaning and rinsing stages of the cycle during the test runs for evaluation of chemical disinfection efficacy.

In either case the exposure to disinfectant solution and then its removal with rinse water will also cause the physical removal of microorganisms and the extent to which this occurs should be evaluated as part of the validation of the test method.

G.3 Validation of the test method

Validation of the test method should demonstrate:

a) the ability to produce a reproducible population of microorganisms (on the surface to be disinfected) by the chosen inoculation method; this should include determination of the loss of viable organisms as the inoculum dries on to the surface;

b) the extent to which these organisms are lost from the surface by the physical action of the disinfection and post-disinfection rinsing process; during evaluation of this effect it is necessary to ensure that any surfactants/detergents normally present in the disinfectant, or any similar effect of the disinfectant moiety, are evaluated.

NOTE 1 This may be undertaken by

1) preparing a solution of surfactant and estimating its antimicrobial activity against the test organisms using an *in vitro* suspension test;

2) evaluating and comparing the extent of removal with water and with a surfactant solution (after correction for the "error" caused by the previously determined inactivation effect);

3) the ability to neutralize the disinfectant; the neutralizer solution will then be used instead of water for the post-disinfection rinse (the extent to which organisms are physically removed by the neutralizing rinse will also need to be evaluated);

4) the extent to which the remaining microorganisms are detected (or removed) by the recovery method.

NOTE 2 Methods in which:

1) suspensions of microorganisms are flushed through the lumen of a device and are assumed to adhere in large numbers;

2) the device(s) are then exposed to liquid disinfectants flushed through the lumen which it is assumed does not physically remove any of the deposited microorganisms;

3) evaluation for the lethal effect of the disinfectant is carried out by flushing the lumen with an eluate solution which it is assumed removes close to 100 % of the surviving population and then numerating the viable microorganisms in the eluate

are unacceptable in the absence of systematic validation and justification for each of the assumptions made.

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