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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

ICS 11.080.10

ISO/CEN PARALLEL ENQUIRY

This draft International Standard is a draft European Standard developed within the European Committee for Standardization (CEN) and processed under the CEN-lead mode of collaboration as defined in the Vienna Agreement. The document has been transmitted by CEN to ISO for circulation for ISO member body voting in parallel with CEN enquiry. Comments received from ISO member bodies, including those from non-CEN members, will be considered by the appropriate CEN technical body. **Accordingly, ISO member bodies who are not CEN members are requested to send *a copy* of their comments on this DIS directly to CEN/TC 102** (DIN, Burggrafenstraße, 6 D-10787 Berlin) **as well as returning their vote and comments in the normal way to the ISO Central Secretariat.** Should this DIS be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month FDIS vote in ISO and formal vote in CEN.

In accordance with the provisions of Council Resolution 15/1993 this document is circulated in the English language only.

Conformément aux dispositions de la Résolution du Conseil 15/1993, ce document est distribué en version anglaise seulement.

Contents

Page

Foreword

This document (prEN ISO 15883-4:2003) has been prepared by Technical Committee CEN/TC 102, "Sterilizers for medical purposes", the secretariat of which is held by DIN, in collaboration with Technical Committee ISO/TC 198 "Sterilization of health care products".

This document is currently submitted to the parallel Enquiry.

EN ISO 15883 consists of the following Parts under the general title “Washer-Disinfectors”.

Part 1: General requirements, definitions and tests.

Part 2: Requirements and test for washer-disinfectors, employing thermal disinfection, for surgical instruments, anaesthetic equipment, hollowware, utensils, glass ware 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 thermo-labile endoscopes.

Other fields of application within the scope of CEN/TC 102/WG 8 include laboratory, veterinary, dental, and pharmaceutical applications. Performance and test requirements for these applications may be specified in other Parts of this standard (to be produced later).

Annexes A, B, and D are normative parts of this European Standard. Annexes C, E and ZA are given for information only.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

In respect of potential adverse effects on the quality of drinking water intended for human consumption, caused by the product covered by this standard:

a) this standard provides no information as to whether the product may be used without restriction in any of the member states of the EU or EFTA;

b) it should be noted that while awaiting the adoption of verifiable European criteria existing national regulation concerning the use and/or the characteristics of the product remain in force.

Introduction

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

This standard is the fourth part of a series specifying the performance of washer-disinfectors and specifies the particular requirements for performance applicable to washer-disinfectors employing chemical disinfection for thermo-labile endoscopes.

The washer-disinfectors specified in this standard 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.

This standard 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.

Requirements for washer-disinfectors for other applications are specified in other Parts of this standard.

Safety requirements for washer-disinfectors are given in IEC 61010-2-045.

1 Scope

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

NOTE 1 WDs complying with this part of prEN ISO 15883 may also be used for cleaning and chemical disinfection of other thermo-labile re-usable medical devices for which the device manufacturer has recommended this method of disinfection.

WDs complying with the requirements of this Part 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 prEN ISO 15883-1:2003, 4.1.5).

The specified performance requirements of this Part are not intended to ensure the inactivation or removal of the causative agent(s) (prion protein) of Transmissible Spongiform Encephalopathies.

NOTE 2 Many disinfectants are known to fix protein and this should be considered when prion protein may be present.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

prEN ISO 15883-1:2003, *Washer-disinfectors — Part 1: General requirements, definitions and tests*.

ISO 4064-1, *Measurement of water flow in closed conduits — Meters for cold potable water — Part 1: Specifications.*

ISO 11731:1998, *Water quality — Detection and enumeration of Legionella*.

WHO Guidelines for drinking water quality 1998.

3 Definitions

For the purposes of this Part of prEN ISO 15883, the definitions given in prEN ISO 15883-1:2003 apply together with the following:

3.1
air break
a physical separation in water supply pipes to prevent back syphonage into the water supply from a device connected to it (see EN1717)

3.2
inoculated carrier
a carrier on which a defined number of test organisms has been deposited[1)] [EN 866-1:1997]

1) EN 866-1 is currently under revision (Vienna Agreement), see ISO/CD 11138-1.

3.3
leak test
a 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 slight positive pressure

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

3.5
minimum effective concentration
the concentration of disinfectant which, under the stated conditions of temperature and time, will meet the required microbicidal performance

3.6
self-disinfection cycle
an operating cycle under the control of the automatic controller, for use without any load in the WD, 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 single-use, multi-dose, containers used to provide process chemicals for use in the WD.

3.7
thermo-labile device
heat sensitive device
a re-usable device for which the temperature to which it may be exposed without damage precludes the use of thermal disinfection

4 Performance requirements

4.1 General

4.1.1 The requirements of prEN ISO 15883-1:2003 apply with the exception of sub-clauses :

— 4.3.1 (specification for thermal disinfection);

— 5.3.2.5 (microbial quality of final rinse water – amended in this Part);

— 6.4.2 (test for quality of final rinse water – amended in this Part);

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

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

— 6.8.2 (load temperature test – amended in this Part);

— 6.10 (cleaning efficacy test – amended in this Part);

which have been replaced or modified in this Part.

4.1.2 This standard deals with three aspects of WD performance. It specifies

a) performance requirements for the WD,

b) methods for reference tests used to verify that the WD meets the specified requirements, and

c) methods for tests that may be carried out to verify continued compliance of the installed WD with the validated process conditions.

The attention of WD manufacturers is drawn to clauses 4, 5, 7 and 8 in relation to specified requirements and Clause 6 for methods of test that may be used to verify that the WD meets the specified requirements.

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

a) leak testing (when appropriate see 4.2.1);

b) cleaning;

c) rinsing (when appropriate);

d) disinfecting;

e) removing toxic residues (when appropriate);

f) drying (when appropriate see 4.6.1).

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

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

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

NOTE 1 When specified by the device manufacturer and / or WD manufacturer pre-treatment or dis-assembly may be required.

NOTE 2 The efficacy of cleaning and disinfection depends on a number of factors which include

a) the nature 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, duration);

e) the detergent system;

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

4.1.5 The value of any process variable which affects the efficacy of the cycle shall be pre-set and adjustment shall require the use of a key, code or tool. (See also 5.18.8 and 5.18.12 of prEN ISO 15883-1:2003)

4.1.6 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 Clear, permanent labelling of the connection system may be deemed to satisfy this requirement with the prior agreement of the user (see clause 10).

4.1.7 The WD manufacturer's instructions shall recommend that, heat-stable endoscopic accessories to thermo-labile devices should be thermally disinfected and/or sterilized. (see clause 8 and prEN ISO 15883-1:2003, 4.1.5)

4.2 Leak test

4.2.1 The requirements of this clause 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 should only be regarded 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 either be provided with

a) means to carry out an automatic leak test on the endoscope which shall be completed before the load comes into contact with water or aqueous solutions, 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 may be used for determining the integrity of the endoscope when appropriate.

NOTE 2 WDs with an automatic leak test may 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.

NOTE 1 Variations in temperature may adversely affect the sensitivity of the leak test and the WD manufacturer should state the maximum temperature range permitted.

NOTE 2 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.

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 intended for the leak test cannot be connected to the irrigation system of the device's channel(s);

— 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 pressurise the device during each leak test shall be provided with means to prevent over-pressurisation of the device in the event of the failure of the pressure control system;

— the extent and duration of pressurisation and the pressure drop or air flow which will be used to indicate a fail 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 The ability of the automatic leak test to detect a leak shall be verified by testing in accordance with 6.4.

4.3 Cleaning

4.3.1 General

All surfaces (internal and external) of the devices which are required to be disinfected by the WD shall be cleaned.

NOTE Some devices have component parts (e.g. electronic connectors) which their manufacturer recommends should not be immersed in water or aqueous solutions. These component parts should be manually cleaned 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 4.1.4 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 may be recommended 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 detergent solution shall be discharged during or after each process cycle and shall not be reused.

4.3.4 Post-washing rinsing

Rinsing between cleaning 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 chemical disinfectant, except as provided for in 4.1.4.

The rinse water quality shall be specified by the WD manufacturer.

NOTE This should be of, at least, potable quality.

4.3.5 Determination of cleaning efficacy

Cleaning shall be deemed to be completed satisfactorily when the chosen test soil(s) are no longer detectable by the assessment method(s) specified (see 6.10).

4.4 Disinfecting

4.4.1 General

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 6.11.5 under the specified conditions of disinfectant concentration, temperature and contact time the required microbial reduction factor is attained.

The choice of disinfectant shall ensure that the spectrum of activity is appropriate for the intended use and that the extent of microbial inactivation during the entire process is sufficient to achieve the overall microbial reduction required.

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 1 Tests conducted on disinfectants should 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. (These conditions may be simulated by the use of validated accelerated ageing when necessary).

NOTE 2 Other process chemicals, e.g. detergents may 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 microbicide. Other systems based on gaseous microbicides are not excluded; equivalent tests would be required.

4.4.2.2 The efficacy of the disinfectant shall be demonstrated by *in vitro* tests (see 6.11.1).

4.4.2.3 When tested 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 $\log_{10}6$ reduction in population of vegetative bacteria including mycobacteria, yeasts and yeast-like fungi;

b) at least a $\log_{10}4$ reduction in population of fungal spores and viruses.

NOTE The reduced requirement in respect of fungal spores and viruses is based on recognition of the practical difficulty of working with high titres of these organisms to reliably demonstrate higher levels of inactivation.

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

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

4.4.2.5 Demonstration by the disinfectant manufacturer that the disinfectant meets the above requirements may be made employing methods described in relevant published standards (e.g. prEN 13727, prEN 14348, AOAC sporicidal test, etc).

4.4.2.6 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 4.4.1.

4.4.3 Temperature

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

NOTE This may be achieved by a) controlling the temperature of the disinfectant solution or b) where appropriate, by operating the WD at ambient temperature with means to prevent operation of the WD when the ambient 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 established 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) of the disinfection stage on each cycle shall not be used to meet this requirement.

NOTE Confirmation of the concentration of disinfectant may require e.g. measurement of the volume of disinfectant admitted together with a certificate of conformity for the concentration of the disinfectant supplied, together with data to support the shelf life, expiry date etc.

4.4.5 Disinfectant use

Whenever practicable the disinfectant solution should be discharged at the end of the process cycle.

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 recommend the disinfectant(s) to be used;

b) 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. the concentration of the active ingredient and adjuvants that may also affect performance;

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

c) 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.

4.5 Final (Post-disinfection) rinsing

4.5.1 The chemical purity of the rinse water used after the disinfection stage shall be of, at least, that specified for potable water in the WHO Guidelines for drinking water quality 1998 (see also prEN ISO 15883-1:2003, 5.23).

4.5.2 The rinse water shall, when tested, by the methods given in Annex A, be free from aerobic mesophilic micro-organisms including legionella and mycobacteria at the point of discharge to the WD chamber and the device(s) to be processed.

NOTE 1 The following methods may be suitable for control of the microbial contamination of rinse water. The rinse water should be:

— maintained in a dedicated reservoir at a temperature not less than 60°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