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## Washer-disinfectors —

### Part 2:

Requirements and tests for washer disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, hollowware, utensils, glassware, etc.

*Laveurs désinfecteurs —*

*Partie 2: Exigences et essais pour laveurs désinfecteurs destinés à la désinfection thermique des instruments chirurgicaux, du matériel d'anesthésie, des récipients, des ustensiles et de la verrerie, etc.*

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ICS

English version

Washer-disinfectors - Part 2: Requirements and tests for  
washer-disinfectors employing thermal disinfection for surgical  
instruments, anaesthetic equipment, hollowware, utensils,  
glassware, etc. (ISO/DIS 15883-2:2003)

Reinigungs-/Desinfektionsgeräte - Teil 2: Anforderungen an  
und Prüfungen von Reinigungs-/Desinfektionsgeräten mit  
thermischer Desinfektion für chirurgische Instrumente,  
Anästhesiegeräte, Gefäße, Utensilien, Glasgeräte usw.  
(ISO/DIS 15883-2:2003)

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 102.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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## Foreword

This document (prEN ISO 15883-2:2003) 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 tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, hollowware, 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 thermo-labile endoscopes*

Fields of application within the scope of EN ISO 15883 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.

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 the potential adverse effects on the quality of water intended for human consumption caused by the washer-disinfector:

- a) this standard provides no information as to whether the washer-disinfector may be used without restriction in any of the member states of the EU or EFTA;
- b) it should be noted that, until verifiable European criteria are adopted, existing national regulations concerning the use and/or the characteristics of the washer-disinfector remain in force.

Annexes A and ZA are given for information only.

## Introduction

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

This part of prEN ISO 15883 is the second of a series specifying the performance of washer-disinfectors and specifies the general requirements for performance applicable to instrument washer-disinfectors. The requirements given in this part apply to washer-disinfectors used for the cleaning and thermal disinfection of medical devices intended for re-use such as:

- surgical instruments;
- powered devices;
- instrument trays;
- instruments for minimally invasive surgery;
- rigid endoscopes;
- anaesthetic and respiratory equipment;
- hollowware;
- glassware;
- containers for transit.

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

When processed in the instrument washer-disinfector, the medical devices may be intended for immediate use or may be intended to be packed and sterilised. In both cases the efficacy of the cleaning and disinfection is of major importance. In the first case this is for the well being of the patient, in the latter case it is for the safety of the staff who handle the instruments in the process of inspecting, testing and packing the instruments.

The efficacy of disinfection may be impaired if soil removal is incomplete before the start of the disinfection process. Users should be aware that some medical devices may require pre-treatment e.g. soaking, brushing, ultra sonic pre-cleaning, lumen irrigation or any combination of these techniques. A number of medical devices may be excluded from processing in a washer-disinfector altogether. Manufacturers of washer-disinfectors are recommended to be very clear about the medical devices that can not be processed in the washer-disinfector.

Reference should be made to the medical device manufacturer's instructions for reprocessing (see also prEN ISO 17664).

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

## 1 Scope

This part of prEN ISO 15883 specifies particular requirements for washer disinfectors (WD) that are intended to be used for the cleaning and thermal disinfection, in a single operating cycle, of re-usable medical devices such as surgical instruments, anaesthetic equipment, hollowware, utensils and glassware.

NOTE Thermal disinfection may be achieved by rinsing the load with hot water, exposure to steam or combination of the two.

The requirements in this part apply in addition to the general requirements specified in prEN ISO 15883-1:2002.

## 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).

EN 1281-1:1997, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets.*

EN 1782:1998, *Tracheal tubes and connector.*

EN 1820:1997, *Anaesthetic reservoir bags.*

EN 10088-2, *Stainless steels — Part 2: Technical delivery conditions for sheet/plate and strip for general purposes.*

EN 12342:1998, *Breathing tubes intended for use with anaesthetic apparatus and ventilators.*

EN ISO 4017:2000, *Hexagon head screws; product grades A and B.*

prEN ISO 15883-1:2002, *Washer-disinfectors — General requirements, definitions and tests.*

## 3 Terms and definitions

For the purposes of this part of prEN ISO 15883, the terms and definitions given in prEN ISO 15883-1:2002 and the following apply.

### 3.1

#### **anaesthetic and respiratory accessories**

respiratory tubes, re-breathing bags and other anaesthetic products that will not be sufficiently flushed by rotating spray nozzles, but which require positioning over fixed spray/jet nozzles

### 3.2

#### **hollowware**

bowls, dishes and receivers intended to contain liquids

### 3.3

#### **lumen devices**

devices which consist of tubes, pipes (either single or coaxial combined) which require connecting to the washer-disinfecter by means of dedicated connectors

### 3.4

#### **powered devices**

surgical instruments which give a rotating and/or oscillating movement to other surgical instruments

NOTE The power applied to the driven instrument may be mechanical (from a motor, either through direct coupling, flexible axle or belt) or by the flow of a pressurised fluid.

EXAMPLES Dental hand pieces, orthopaedic saws and drills.

### 3.5

#### **washing time**

period for which the cycle variables (e.g. temperature of the load, detergent concentration in the chamber) are maintained at or above the values specified for washing

### 3.6

#### **washing temperature**

minimum temperature of the washing temperature band

### 3.7

#### washing temperature band

range of temperatures, expressed as the washing temperature and the maximum allowable temperature which may prevail throughout the load during the washing time

## 4 Performance requirements

### 4.1 General

4.1.1 The requirements of prEN ISO 15883-1:2002 apply with the exception of

- subclause 4.3.2 (which refers to chemical disinfection; see Scope);
- subclause 5.7.6 (which refers to the accuracy of dosing systems; see 4.1.6).

4.1.2 The washer-disinfector shall be designed to clean and thermally disinfect specified medical devices which are intended by the manufacturer of the medical device to be reused.

4.1.3 The devices shall be cleaned and disinfected on the outer surfaces and where necessary for their safe use, safe handling and/or correct functioning, the inner surfaces.

4.1.4 When necessary the washer-disinfector shall be provided with means to facilitate correct alignment of the load in the washing chamber.

4.1.5 In order to process lumen and/or powered devices the washer-disinfector shall be provided with the necessary connectors and load carriers which shall be designed to ensure an adequate flow of water and process chemicals to each device.

4.1.6 The means to control the volume of the process chemical(s) admitted (see prEN ISO 15883-1:2002, 5.7.5 and 5.7.6) shall be adjustable by means of a key, code or tool and shall deliver the set volume to an accuracy of  $\pm 5\%$  or better.

### 4.2 Cleaning

4.2.1 Cleaning shall be tested in accordance with the requirements of prEN ISO 15883-1 using the test soils specified in prEN ISO 15883-1:2002, Annex B that are pertinent to the loads to be processed.

4.2.2 During the washing stage

- the washing time shall start when the temperature at the control sensor of the washer-disinfector reaches the specified washing temperature;
- the washing temperature band shall have the lower limit defined by the washing temperature and an upper limit of, no greater than, washing temperature + 10 °C (see prEN ISO 15883-1:2002, 4.2.3).

Throughout the washing time the temperatures on any surface of the load, chamber walls, chamber drain and the load carrier shall:

- be within the washing temperature band;
- not differ from one another by more than 5 K.

NOTE A washing stage may include two or more washing temperatures and washing temperature bands.

### 4.3 Disinfecting

**4.3.1** The cycle shall include a thermal disinfection stage for which the time at which the load is maintained at the disinfection temperature gives an  $A_0$  of at least 600 on all surfaces of the load to be disinfected when tested in accordance with 6.3.

**4.3.2** The cycle shall include a thermal disinfection stage giving an  $A_0$  of at least 600 on all the internal surfaces of the chamber and on the load carrier when tested in accordance with 6.3.

**4.3.3** The WD shall provide for disinfection times and temperatures to be set to give an  $A_0$  value up to a maximum value of not less than 3000.

NOTE The choice of  $A_0$  and disinfection temperature will depend upon:

- the intended use of the load items;
- the materials of which the load items are made;
- the nature and extent of the bioburden on the load items with particular reference to heat resistant infective organisms.

Users should seek advice from those with responsibility for control of infection.

**4.3.4** If the disinfection is done with steam, the temperature on the surfaces of the load, chamber walls, drain or the free chamber space shall remain below the boiling point of water corresponding to the pressure in the WD chamber in order that water remain on the surface of the device to be disinfected.

Compliance shall be established by examination of the data obtained from thermometric testing (see 6.3).

### 4.4 Temperature of internal surfaces of processed devices

For anaesthetic and respiratory tubing, lumen devices and powered devices, the temperature of the inner surfaces shall be deemed to have been achieved when:

- the temperature of the process fluids at the connection to the devices is within the limits specified by the manufacturer of the washer-disinfector and in compliance with 4.2 and 4.3;
- the flow of the process fluids at the connection to the instrument is within the limits specified by the manufacturer when tested in accordance with 6.3.3;
- the calculated heat capacity of the water flowing through the instrument is sufficient to heat the instrument to the disinfection temperature before the start of the disinfection time;
- the results from the cleaning tests as described in 6.2 are acceptable.

## 5 Mechanical and control requirements

### 5.1 Load connectors

#### 5.1.1 Connectors for powered devices

For powered devices, in which the internal surfaces are intended to be flushed, the WD or load carrier shall be fitted with connectors, specified by the manufacturer of the powered device, providing means to drive the instrument during the cycle. The speed of rotation shall be chosen to ensure that all internal surfaces of axles, gears etc. come into contact with the process fluids for the specified times.



### 5.1.2 Verification of flow through lumen and powered devices

5.1.2.1 During the washing, disinfection and rinsing stages it is necessary for the various process fluids to 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:

a) by 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; or

b) by the automatic controller providing means to verify the flow of process fluids through each channel. Failure to achieve the required flow through each channel shall cause a fault to be indicated.

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

## 5.2 Control systems

5.2.1 Means shall be provided to pre-set the washing temperature over a range between room temperature and to 60 °C or higher. Adjustment shall be by means of a code key or tool.

5.2.2 Means shall be provided to pre-set the disinfection temperature over a range between 75 °C and not less than 95 °C. Adjustment shall be by means of a code key or tool.

5.2.3 Means shall be provided to pre-set the disinfection time over the range from 1 min to at least 60 min. Adjustment shall be by means of a code key or tool.

NOTE WDs of the pass through type should be employed when practicable to provide separation of cleaned and disinfected items from those awaiting processing.

## 5.3 Process verification

The WD shall be equipped with a temperature recorder, with sensors and signal processing independent from the controller, to record the attainment of the programmed disinfection conditions (see prEN ISO 15883-1:2002; 5.11.4 b)).

## 6 Testing

### 6.1 General

Testing for conformity shall be carried out in accordance with prEN ISO 15883-1:2002, clause 6.

### 6.2 Tests for soil removal from chamber walls, load carrier and load

The tests shall be carried out in accordance with prEN ISO 15883-1:2002, 6.10 using one or more of the test soils and reference loads, as appropriate, specified in prEN ISO 15883-1:2002, Annex B.

### 6.3 Thermometric tests

#### 6.3.1 General

The tests shall be performed in accordance with prEN ISO 15883-1:2002, 6.8 with the modifications given below.