Efficacious washing and disinfection that complies with the envisaged specifications (point 2, fig. 1) is a fundamental part of a treatment and decontamination process of the medical device if the safety of both the operator who carries out the process and that of the patient is to be safeguarded, and if sterilising (point 6, fig. 1) is to be obtained: only efficaciously washed and disinfected instruments can be sterilised correctly (ref. §2, “Hygiene in Klinik und Praxis”, mhp – Verlag, 2004). Increasingly greater attention has therefore been paid to this phase of the treatment cycle of the medical device and the machines most able to carry out this task are automatic washing and disinfection machines or Washer Disinfectors, as the standard defines.

Remember that, when it comes to general and “safety” requirements, the Washer Disinfector sector is covered by the Directive 93/42/EEC, and by the standard IEC 61010-2-045 which has already been in force for several years and according to which SMEG’s Washer Disinfectors have been designed and manufactured.

The term pr EN ISO 15883 stands for a draft standard concerning the actual technical requirements that the Washer Disinfectors (called “WD” from now on) and their accessories must meet as far as performance is concerned, in order to guarantee that the washing and disinfecting cycles are controllable*, verifiable** and can be repeated***. These cycles can be used for treating the reusable medical devices utilised in medical, dental, pharmaceutical and veterinary practices.
At the present time, pr EN ISO 15883 is divided into five parts, the first two of which specifically concern WD. They are:

- **15883-1** Washer-disinfectors – Part 1: General requirements, definitions and tests.
- **15883-2** Washer-disinfectors – Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, hollowware, utensils, glassware, etc.

These two parts contain a detailed list of the technical requirements according to which the WD must be designed as well as the tests they must undergo in order to obtain conformity certification. A few of the more important and particular concepts in the text of the standard, that outline its philosophy, are illustrated below:

- a more precise control over the fundamental physical parameter involved, i.e. the temperature, by means of a double measuring system (to guarantee a controllable washing cycle*)

- verifiability of the temperature measurements thanks to the ability to install external sensors inside the washing chamber (to guarantee a verifiable washing cycle**)

- control of the dispensing system for the chemicals required for washing through accurate measurement of the parameters involved (to guarantee a controllable washing cycle*)

- reliability of the automatic control of the washing system by means of several microprocessors (to guarantee a controllable washing cycle*)

- the criterion according to which the expected efficacy of the disinfection cycle is evaluated: the standard defines a parameter \( A_0 \) for the relative cycle

- the integrity of the process ensured by the automatic interlock door mechanism, cancellation and consequent repetition of the cycle after an unforeseen interruption (to guarantee that a washing cycle can be repeated***)

- the safety of the process. All the significant data concerning the individual cycles are memorised and filed by means of: printer/on-line storage, connection to an external PC (to guarantee a verifiable washing cycle**)

- identification and consequent responsibilisation of the worker/s by means of a code or user password (to guarantee a controllable washing cycle*)

We would now like to go on to describe the \( A_0 \) concept (see Tab. 1 on the next page) drafted by pr EN ISO 15883, which explains the meaning of the temperature and time values indicated in the thermal disinfection programs.
A stands for the equivalent time in seconds required to produce a given disinfection effect at a temperature of 80°C (taken as a reference). If D is the time required to reduce the bioburden on the instrument treated by a factor 10 (thus with a 90% “lethality” degree) at a particular temperature, value z can be expressed as the temperature increase (in K degrees) required to reduce D by a factor 10. In view of this, A₀ stands for the value of A when the temperature is 80°C and value of z is equal to 10.

In short, the value of A₀ expresses the degree of “lethality” in seconds at a temperature of 80°C, released by the thermal disinfection process to the medical device, with reference to microorganisms that possess a z value of 10 (a characteristic valid for many microorganisms). The A₀ value that must be obtained depends on both the type and number of microorganisms on the contaminated medical device and on its successive use.

According to pr EN ISO 15883 and the recommendations of the Robert Kock Institute (European authority on the subject), an A₀ of 600 is considered as the minimum standard for non-critical medical devices, i.e. for those that only come into contact with uninjured skin. A further condition required is that microbic contamination must only be slight and there must be no heat-resistant pathogens present. An A₀ value of 600 can be obtained by maintaining a temperature of 80°C for 10 minutes or 90°C for 1 minute or again, 70°C for 100 minutes.

If the medical devices are contaminated with heat-resistant viruses, such as those of hepatitis B, the value of A₀ must be at least 3000. This can be obtained by maintaining a temperature of 90°C for 5 minutes.

An A₀ value of 3000 is considered the minimum value to apply to all medical devices considered to be critical. Programs that include thermal disinfection have therefore been designed to offer the following A₀ values:

<table>
<thead>
<tr>
<th>Temperature and Time</th>
<th>A₀</th>
</tr>
</thead>
<tbody>
<tr>
<td>90°C 1’</td>
<td>600</td>
</tr>
<tr>
<td>90°C 5’</td>
<td>3000</td>
</tr>
<tr>
<td>93°C 5’</td>
<td>6000</td>
</tr>
<tr>
<td>93°C 10’</td>
<td>12000</td>
</tr>
</tbody>
</table>

For the sake of convenience, the formula for calculating A₀ is given below

\[ A₀ = τ \cdot 10^{\left(\frac{T-80}{10}\right)} \]

Where:
- τ = time in seconds for which the disinfection temperature must be maintained
- T = disinfection temperature in °C

In view of the above, it is easy to understand what the intention of the authors of the standard is to guarantee that a medical device subsequently claimed as “conforming to EN/ISO 15883”, effectively assures an efficacious washing and disinfection process that complies with precisely defined and objective evaluation criteria.
A description is given below of the characteristics of the model WD5090 Washer Disinfector, which fully reflect the previously indicated points:

- double temperature sensor required for measuring the temperature in the chamber and for ensuring that the measured values are reliable through cross-checking

- duct for inserting a group of probes that measure the temperature inside the washing chamber
• dispensing system with redundant monitoring: timed control, flowmeter, level sensor, conductivity sensor, dispenser current input sensor

1. Motherboard;  
2. Level sensor;  
3. Flowmeter;  
4. Peristaltic pump;  
5. Conductivity sensor

• monitoring system with four microprocessors: process management, machine inputs/outputs, display/keyboard, communication with the “outside world”, ability to file and download into a PC via parallel port, RS232 serial port, USB serial port, LAN connection, at least 100 cycles at a time with “memory full” indication on the display

1. Parallel port;  
2. RS-232 serial port;  
3. USB serial port;  
4. LAN connection;  

1. Bi-processor motherboard;  
2. Microprocessor type interface board;  
3. Microprocessor type communication board
• Printouts can be obtained through the built-in printer installed inside the detergent cabinet

• electric door lock, detection of about one hundred alarms, cycle cancelled if interrupted
• wide choice of programs with $A_0$ from 600 to 12000 (see Table 1, page 4)
• four password levels (worker, person in charge of the disinfection/sterilisation unit, authorised technician, Smeg)

Consult the technical data sheet for a detailed and complete list of all the features included.

Alongside these technical innovations, the product also features the known characteristics that distinguish all Smeg’s products: quality of the materials, reliability of the components, easy use, accurate design.

Thus everything has been created, developed and manufactured to offer the public an innovative product that complies with the most recent standards, in Italian industry’s very best quality traditions.
WD5090: Washer disinfector

- Wash tank/door in AISI 316L, acid resistant chrome-nickle-molibdenum stainless steel
- External panels in stainless steel AISI 304
- External dimensions: lxdxh 900x630x850 mm
- Useful wash tank dimensions: lxdxh 520x515x545 mm
- Washing levels with trolleys equipped with rotating spray arms
- Total washing surface: 0.52-1 m²
- Controlled by 4 microprocessors
- Electronic clock and datary
- 20 standard programs according to the A0 chosen
- 10 programs can be freely compiled by the end user (can be extended up to 50)
- passwords levels: operator, person in-charge, authorised technician, Smeg
- Automatic cycle counter
- Up to 100 complete cycles can be stored
- Download of files with indication if memory is full
- RS-232, USB, PARALLEL, LAN interface
- Retro-illuminated graphic LCD module (128 x 64 pixel)
- User friendly membrane keyboard with a clear difference between functional keys and keys for inserting data
- Panel mounted printer installed
- Recirculation wash pump: 400 l/min
• Detergent racks installed in the side cabinet: capacity four 5 litre cans
• 1 peristaltic pump for liquid alkaline detergent
• 1 peristaltic pump for liquid neutralizer
• 2 peristaltic pumps for dispensing auxiliary liquid additives
• 1 extra peristaltic pump for connecting an external can
• Dispensing controlled by means of flow meters, level sensors, current sensing, timing and conductivity sensors
• Separate cold, hot and demineralised water connections 1.5 - 5 bars
• Non-pressurised demineralised water may be used: booster pump supplied on request
• Incoming water supply controlled by flow meters
• Water consumption: 8/10 litres per phase according to the program/trolley used
• Built-in water softener with automatic volumetric regeneration
• Regeneration salt refill with signalling on the display
• Cycle control in real time with the visualisation of the current phase, elapsed time and temperature
• Double temperature control with cross checking of the values measured
• Maximum temperature allowed controlled electronically
• Calibration of temperature sensors indicated on the display
• 100 types of alarms with immediate visualisation on the display
• Diagnostic menu input/output
• Safety features: wash cycle interrupted if door is opened, water level control, heater safety, door lock controlled by the microprocessor
• Panel mounted three phase switch
• Water electrically heated
• Duct for introducing external probes in the wash chamber
• Vapour condenser installed
• Hot forced air drying with fan speed control
• Drying prefilter class C 98%
• Drying absolute HEPA filter class S 99.999%
• “Change filter” indication on the display
• Possibility to reduce drain water temperature
• Alternative draining can be selected (to avoid environmental problems)
• Software traceability Smeg (optional, code WDTRACE) with the possibility of proving a posteriori the value of $A_0$ obtained and to view the time/temperature graph of the process chosen

**Power supply:**
• 3/N/PE 50Hz 400V 7kW
• 1/N/PE 50Hz 230V 2.8kW
WD5090 accessories

The trolleys and accessories indicated are only some examples of the range available: the Washer Disinfector, WD5090, can be used with other trolleys present in the catalogue “Instrument washers for Operating Theatres” dedicated to the models GW3050H, GW4050H and GW5050H.

**CSK4 SURGICAL INSTRUMENT TROLLEY**
Washing trolley for surgical instruments. Suitable for treating standard and large-sized surgical instruments. Two washing levels served by an incorporated sprayer and a sprayer on the bottom of the machine. To be fitted with N.4 CSK2 baskets. Made of stainless steel.

**CSK2 SURGICAL INSTRUMENT BASKET**
Surgical instrument basket with handles. Occupies 1/2 level of CSK4. Dimension LxDxH 450x225x50 mm., mesh 5x5 mm. Made of stainless steel.

**CSK 6 SURGICAL INSTRUMENT TROLLEY**
Washing trolley for surgical instruments. Suitable for treating large quantities of standard-sized surgical instruments. Three washing levels served by two incorporated sprayers and one sprayer on the bottom of the machine. To be fitted with N.6 CSKDIN baskets. Made of stainless steel.

**CSK DIN SURGICAL INSTRUMENT BASKET**
Surgical instruments basket with handles. Occupies 1/2 level of CSK6. Dimension LxDxH 480x245x50 mm., mesh 5x5 mm. Made of stainless steel.

**CSK 8 SURGICAL INSTRUMENT TROLLEY**
Washing trolley for surgical instruments. Suitable for treating standard and large-sized surgical instruments. Four washing levels served by three incorporated sprayers and one sprayer on the bottom of the machine. To be fitted with N.8 CSK2 baskets. Made of stainless steel.

**CSK2 SURGICAL INSTRUMENT BASKET**
Surgical instrument basket with handles. Occupies 1/2 level of CSK8. Dimension LxDxH 450x225x50 mm., mesh 5x5 mm. Made of stainless steel.
Technical Data Sheet WD5090

**Electronic Control**
- 4 microprocessors

**Standard Programs Stored**
- 20

**Programmable**
- 10 (expandable to 50)

**Retro-illuminated LCD Graphic Display**
- 128 x 64 pixel

**Clock and Datary**
- Yes

**Re-programmable Phases**
- 6

**Phase Parameters**
- Type of water, quantity of detergents, temperature, holding time in minutes, drying temperature and time

**Temperature in the Wash Chamber**
- From 5°C to 95°C

**Precision**
- 0.1°C

**Temperature Sensors in the Wash Chamber**
- 2 PT 1000 Classe B IEC 60751 + possibility for a third one

**Visualization of Time**
- 5 digits

**Dosing Pumps (0-220 ml)**
- 4

**Optional Dosing Pump (0-220 ml)**
- 1

**Door Safety Lock**
- Yes, electromagnetic interlock

**Safety Features**
- Three phase switch, safety thermostats, redundant dosing system control, redundant temperature control, incoming water control through flow meters etc.

**Alarm Indications**
- 100

**Fault Finding Menu**
- Yes

**Program Modification**
- Yes (through password)

**Password**
- 4 levels

**Languages**
- 4: Italian, English, French, German, (on request: Spanish, Polish, Swedish, Russian, Japanese)

**Auxiliary Functions**

**Duct for External Probes**
- Yes

**Wash Separation Control**
- Yes

**Output Parallel Printer**
- Yes

**Serial Port**
- Yes

**Serial Port USB**
- Yes

**LAN Connection**
- Yes

**Cycle Recording**
- Yes

**Download of Cycles Recorded**
- Yes

**Drying System**

**Fan Motor**
- 0.25 kW

**Heater**
- 2.5 kW

**Pre-filter Class C 98%**
- Yes

**Absolute HEPA Filter Class S 99.999%**
- Yes

**Drying Temperature**
- 75°C-100°C

**Water Supply (Pressure 1.5-5 Bar)**

**Cold/Hot Water - Hardness**
- Max 42ºF

**Conductivity Demineralised Water**
- <20 µS/cm

**Booster Pump for Demineralised Water**
- Optional

**Water Softener**
- Yes

**Recycling Pump**
- 400L/Min

**Water Heating**

**Electric**
- 6.3 kW max

**Preheating through Boiler**
- Optional

**Vapour Condenser**
- Yes

**Dimensions LxDxH mm**

**External (without top)**
- 900x630x850 (830)

**Internal**
- 520x515x545

**Net Weight (kg)**
- 120

**Stainless Steel**

**Wash Chamber**
- AISI 316L

**External Panels**
- AISI 304

**Power Supply**

**Voltage / Max Power**
- 1/N/PE 230V ~ 50Hz 2.8 kW
- 3/N/PE 400V ~ 50Hz 7.0 kW

**Noise Level**
- 50dB

**Conformity**