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RECOMMENDATIONS FOR THERMAL DISINFECTION BASED ON THE A_0 CONCEPT ACCORDING TO EN ISO 15883

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ABSTRACT

The use of aseptic instruments for the care of patients is an essential element in the prevention of nosocomial infections. Significant risks have been associated with inadequate or improper cleaning and disinfection of reusable medical devices. Thermal disinfection with moist heat, based on the A_0 concept (EN ISO 15883-1), is the most common method for disinfection of medical devices in the hospital setting. A_0 is a physical parameter denoting the inactivation of microorganisms. The concept of A_0 is intended to allow equivalent disinfection efficiencies to a reference time/temperature to occur at other disinfection temperatures. This paper focuses on parametric control of thermal disinfection - A_0 values as recommended in the standard and their interpretation. The experimental fundamentals regarding of an A_0 concept are rare. Data on thermal disinfection are partly contradictory. The washer disinfectors use thermal disinfection programs set in accordance with the parameters: time and temperature, which is proven suitable biocidal activity, not based on the A_0 value. Many authorities in the field of disinfection recommends to use higher values of A_0 than those specified in the standard EN ISO 15883.

Key words*: decontamination, disinfection, washer disinfector, thermal disinfection*

INTRODUCTION

Ensuring an appropriate level of quality in the management of medical devices affects the prevention of infections and is a legal obligation. Decontamination reusable equipment, including cleaning, disinfection and sterilization are necessary components to prepare the equipment for re-use. Cleaning and disinfection in automatic machine is the most recommended, safe way of treatment of medical equipment after use; such process is repeatable, can be validated, routine supervised and the staff have limited contact with sharps. Washer-disinfector must ensure a reliable and safe to carry out the process. The requirements for washer-disinfectors and accessories for cleaning and disinfection of medical, dental, pharmaceutical, laboratory and veterinary devices are define in standards of the EN ISO 15883. The washer disinfectors can perform cleaning, thermal disinfection at temperature above 60°C or chemo-thermal disinfection (below 60°C, the use of the chemical - disinfectant preparation) (1, 2, 3, 4). Disinfection temperature band is defined -0/+5K (5). This paper focuses on parametric control of thermal disinfection - A_0 values as recommended in the standard and their interpretation.

THE A_0 CONCEPT

The parameters governing thermal disinfection in washer –disinfectors are defined and controlled by the A_0 value in the standard EN ISO 15883-1 (5). ”A” here denotes the time equivalent in seconds at 80°C which generates a certain disinfection action against microorganisms with a defined *z* value. The *z* value is a measurement (in degrees K) of the temperature relationship to the killing process. Based on the definition, the *z* value corresponds to the increase in temperature required to reduce the *D* value of a particular microorganism by 90%. The *D* value is the time required at a particular temperature to kill 90% of a population of the respective microorganisms (decimal reduction time). The *z* value of a microorganism thus increases with growing resistance of this organism. Bacterial spores, which are the most resistant of all microorganism, have an average value

Table I. A_0-values at different temperatures and times

Process temp. (°C)	Holding time for A_0 = 6000		Holding time for A_0 = 3000		Holding time for A_0 = 600		Holding time for A_0 = 60	
	sec	min	sec	min	sec	min	sec	min
70	60 000	1 000	30000	500,0	6000	100,0	600	10,0
80	6 000	100	3000	50,0	600	10,0	60	1,0
90	600	10	300	5,0	60	1,0	6	0,1
93	300	5	150	2,5	30	0,5	3	0,1

of z = 10°C (6). This z value is also employed in the A_0 concept, despite the fact that spores are not an explicit goal targeted by thermal disinfection. Selection of the z value can be seen, however, as a safety reserve when defining disinfection parameters. In the case of z = 10 °C, the term "A_0" is used instead of "A" (6). A particular A_0 value can be achieved with the most diverse temperature/time combinations (Table I).

The mathematic formula for calculation of A_0 is as follows:

$A_0 = \Sigma 10^{(T-80)/z} \times \Delta t$

Δt = selected time period in seconds,

T = temperature of the load in °C (lower limit-value = 65°C, z = 10°C)

In calculating A_0 values, a lower temperature limit for the integration is set at 65°C since for temperatures below 65°C, the z value and D value of thermophilic organisms may change dramatically and below 55°C there are a number of organisms which will actively replicate (5).

SELECTION OF A_0 VALUES

EN ISO 15883 defines two different applications, each with an A_0 value. According to these, human waste containers (Part 3 of the standard) must be disinfected at least with an A_0 = 60 and surgical instruments (Part 2) with an A_0 = 600 (7, 8).

An A_0 = 60 is generally viewed as being an acceptable minimum for devices coming into contact with intact skin (uncritical), provided that these products are not contaminated with large quantities of heat resistant pathogenic microorganisms. This treatment presupposes a low bioburden prior to disinfection as well as the absence of heat-resistant pathogens. Based on the mathematic formula an A_0 = 60 means e.g. 80°C/60 sec or 90°C/6 sec or 70°C/10 min (9).

An A_0 = 600 is stipulated as a minimum requirement for the thermal disinfection of surgical instruments, corresponding to a holding time of 600 sec (10 min) at 80°C or 60 sec (1 min) at 90°C. These disinfection processes deployed against bacteria, including mycobacteria, fungi and heat-sensitive viruses. If efficacy is also to be ensured against heat-resistance viruses e.g. hepatitis B, a corresponding higher A_0 = 3000 corresponding to a holding time of 5 min at 90°C. The washer-disinfector must be capable of achieving this A_0 value, but no application is specified for an A_0 = 3000 in the standard. This interpretations based on a commentary issued by the Robert Koch-Institute (RKI) (6).

DISCUSSION

For many years in Germany and other German speaking countries and also in Poland also there was only one program with a thermal disinfection step - 93°C/10min. This program is known today as BGA or epidemic program. In this program already the first flowing water or the detergent solution must be disinfected. Pre-cleaning without disinfection is therefore not possible. Cleaning is carried out together with thermal disinfection in a first program step. The detergent is added after inflow of the water. Heating and simultaneous cleaning take place during circulation. Until a temperature of approx. 70 °C is reached, residues must be removed from the instruments by rinsing, emulsification, dispersion and disintegration and these must be in as stable a solution as possible, so that they are not deposited again on the instruments during the ensuing circulation and drainage of the detergent solution. If the heating and cleaning phase to 70 °C is executed too quickly, residues remain which can later coagulate in or on the instruments and become insoluble. Some instruments may then not be clean. These conditions (93°C/10 min; A_0 = 11972), formulated by the former German Federal Health Office (BGA, now the RKI), provide bactericidal, fungicidal, tuberculocidal activity and virus inactivating action, including hepatitis B viruses (HBV). Extremely high safety has been incorporated for inactivation of HBV, since not all **Central Sterile Supply Department (**CSSD) staff members will have been vaccinated against HBV. Already in the 80s, the call for disinfection of the first flowing solution was restricted to the occurrence of pathogens with epidemic potential. The medical officer can decree that under certain circumstances only epidemic program be operated. This means that the washer –disinfector must be able to execute this program (10).

The present experimental data permit the conclusion that an A_0 = 600 is sufficient for disinfection of

surgical instruments, etc. when used to counter bacterial contamination or even contamination with HBV (6, 11). In any case, all critical instruments are also sterilized before being used on patients. Routine disinfection with A_0 = 3000 is therefore not justified and, correctly, the standard EN ISO 15883 makes no provision for it. But as a compromise, the following approach could be adopted: all instruments being sterilized after disinfection in the washer-disinfector should be disinfected with an A_0 = 600 (e.g. 1 min/90°C). All semi-critical instruments undergoing thermal disinfection but not sterilization should be disinfected with an A_0 = 3000 (e.g. 5 min/90°C). In the interest of the overall reprocessing outcome, it would often be advantageous to use the time saved on using an A_0 = 600 vs. A_0 = 3000 for the cleaning phase (6).

The experimental fundamentals regarding of an A_0 concept are rare. Data on thermal disinfection are often extrapolations of data gathered from investigations on pasteurization and foodstuff settings (6, 13). Up to now obtained only few studies available on thermal resistance of vegetative bacteria and the suitability of the A_0 concept. Data are partly contradictory.

The investigations conducted by Pisot demonstrated that the A_0 value theory described in EN ISO 15883-1 is confirmed in everyday practice. Reduction of the microbial count of the microorganisms used in these tests at the respective A_0 value revealed that an A_0 value of 60 is enough to assure effective inactivation of the bacteria. Thermal disinfection of medical devices in the hospital setting, which is generally conducted with a process using an A_0 value of 600 or 3000, thus offers a high degree of protection to both personnel and patients against infection (13).

The results of the study conducted by Diab-Elschahawi and co-authors do not support the general recommendation to use an A_0 of 60 for the disinfection of bedpans but warrant differential strategies depending on the expected microbial load. They generally recommend for disinfection processes aimed at vegetative bacteria an A_0 of at least 180 (1 min/85°C). Furthermore it should be emphasized the utmost importance of not allowing freshly contaminated bedpans to dry for longer time periods, as the significance of thorough cleaning of contaminated human waste containers before being exposed to heat treatment for their disinfection. The EN ISO 15883-3 standard recommends an A_0 value of 60 for uncritical medicine products, meaning those products coming into contact solely with intact skin. However, if we look at human waste containers we have to question whether they can always be classified as non-critical medical devices, as patients needing a bedpan are often immobile and might be at higher risk for bedsores in the sacral region. In this case, bedpans would have to be classified as semi-critical medical devices. Moreover in daily hospital routine, human waste containers cannot always be cleaned and disinfected immediately after use as they should be, but are left to dry before being processed. Dried feces are more difficult to remove and soil residues massively impair the disinfection outcome. You can accept an A_0 of 60 for vegetative bacteria provided sufficient previous cleaning of the bedpans and patients without any skin damage in sacral region. As pre-requirements cannot always be ensured, authors recommend for thermal disinfection process an A_0 at least 180 (12).

T. Miorini from Institute for Applied Hygiene (ÖGSV) considers that there is no need to limit the time for inactivation of microorganisms on medical devices to the minimum. The principle of overkill procedures should be retained for sterilization as well for disinfection of MDs. This procedure assures a certain robustness of the reprocessing treatment of MDs under difficult conditions. In Austria the A_0 concept is limited to temperatures above 80°C until more data are available (14).

CONCLUSIONS

An A_0 value which specifies the relations between temperature and exposure time to achieve a defined inactivation of microorganisms is only a theoretical concept.

Programs of thermal disinfection in washer disinfectors should be set in accordance with the parameters: time and temperature, with proven suitable biocidal activity not based on the A_0 value.

An A_0 value can be composed of the sum of many (to several) subvalues (e.g. heat-up phase for thermal disinfection in washer-disinfectors), so the exposure - holding time may be reduced. According to Robert Koch Institute (RKI) recommendation thermal disinfection of surgical instruments adjustable by A_0 should be used the value A_0 = 6000 (6). It seems to be right solution in the present state of knowledge from practical and epidemiological point of view such recommendations should be adopted in other countries, including Poland.

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