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Thermal Disinfection – The A_0 Concept and the Biological Background

This paper focuses on parametric control of thermal disinfection and on its relationship to the biology underlying the killing/inactivation of microorganisms through moist heat. The disinfection parameters (A_0 values) as recommended in the standard, or their interpretation, are cortically reviewed. It would probably be advisable to replace the overkill approach, which is especially prevalent in German-speaking countries, by improved cleaning.

Introduction

The disinfection parameters 93 °C / 10 min for automated instrument processing have long been immutable fixtures for users in the German-speaking countries. This has even resulted in a CSSD staff member once remarking to a technician who had been engaged to change a programme: "You may do what you like so long as the 93 °C/10 min is not altered." But times have changed. More attention is now being paid to cleaning, while at the same time introducing the A_0 concept for thermal disinfection. The users are now hearing about different A_0 values and about very different disinfection parameters from those to which they had been accustomed. This engenders a lack of certainty and prompts the question: "How should thermal disinfection be performed in future?" The following treatises are intended as a means of providing an evidence-based answer to this.

The A_0 Concept

The parameters governing disinfection with moist heat in washer-disinfectors are newly defined and controlled by means of the A_0 value in the standard prEN ISO 15883-1 (Washer-disinfectors – Part 1: General requirements, definitions and tests). This is therefore no longer a biological indicator but rather practically involves measurement of the expended energy (temperature/time) which demonstrates whether or not the disinfection process has generated the desired lethality effect.

"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 °C) 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 in tandem with growing resistance of this organism. Bacterial spores, which are the most resistant of all microorganism, have an average value of z = 10 °C (1). 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". A particular A_0 value can be achieved with the most diverse temperature/time combinations. At the same time, an A_0 value can be composed of the sum of many (to several) subvalues = ΔA_0 (e.g. heat-up phase for thermal disinfection in washer-disinfectors).

The mathematic formula for calculation of A_0 is as follows:

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

(Δt = selected time period in seconds, T = temperature of the load in °C (lower limit-value = 65 °C), z = 10 (°C))

A_0 is thus a physical parameter denoting the inactivation of microorganisms. The question now arises as to which A_0 value is really needed for thermal disinfection in a washer-disinfector. On this subject, prEN ISO 15883-1 specifies:

"An A_0 = 60 is generally viewed as being an acceptable minimum for devices coming into contact with intact skin, provided that it is unlikely that these products are contaminated with large quantities of heat-resistant pathogenic microorganisms. It is stressed that this treatment presupposes a low bioburden prior to disinfection as well as the absence of heat-resistant microorganisms with a potential to cause serious diseases".

An A_0 = 60, based on the formula, means 80 °C/60 sec or 90 °C/6 sec or 70 °C/10 min, etc.

In Part 2 of the standard (thermal disinfection of surgical instruments, etc.) an A_0 = 600 is stipulated as a minimum requirement for the disinfection cycle. It goes on to state that the washer-disinfector must be capable of achieving disinfection values of not less than A_0 = 3000.

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But no application is specified for an A_0 = 3000.

An A_0 = 600 corresponds to 80 °C/ 10 min or 90 °C/1 min or 93 °C/30 sec, etc. An A_0 = 3000 means 80 °C/50 min or 90 °C/5 min or 93 °C/2 min 30 sec, etc.

A current interpretation in respect of the A_0 values to be employed from the German perspective would be as follows:

"For disinfection processes deployed against bacteria, including mycobacteria, fungi and heat-sensitive viruses, an A_0 value of 600 is specified, corresponding to a hold time of 600 sec = 10 min at 80 °C. The A_0 value of 600 can also be achieved at 90 °C with one tenth of the hold time, i.e. 1 minute. If efficacy is also to be ensured against heat-resistant viruses, e.g. hepatitis B, a correspondingly higher A_0 value of 3000 must be chosen, corresponding to a temperature of 90 °C with a hold time of 5 min. It is recommended to select in general the A_0 value of 3000 for programmes used to process surgical instruments." (2)

This interpretation is based on a commentary issued by the Robert Koch-Institute (RKI) in 1999, which apparently presupposed that the RKI view would prevail in the European standard (3).

The A_0 Concept and the Biology

What then are the biological or experimental fundamentals (definition of the kill kinetics) underlying the choice of certain A_0 values for thermal disinfection or, expressed in more modern terms, how are thermal disinfection processes validated? An exploration of this issue has revealed that there are only very limited data available on thermal disinfection and that therefore recourse has to be had to extrapolation of data gathered from investigations on pasteurisation in the foodstuffs setting or in the pharmaceutical industry (blood products). Using the A_0 equation, such data can be converted to reflect the conditions prevailing in the washer-disinfector.

A 5 log reduction (reduction by the factor 10^5 = 100'000) of pathogens is stipulated for a pasteurisation process (4). Typical conditions prevailing in the beverages' industry are 72 °C/15 sec. using the A_0 equation, this corresponds to an A_0 value of 2.37.

But there are particularly heat-resistant bacteria, of which *Enterococcus faecium* is the most important in the healthcare setting. It is the clinical isolates rather than laboratory strains which have proved to be particularly temperature resistant. For example, there are reports of 5 isolates with a reduction factor (RF) < 5 log levels at 65 °C/10 min (A_0 = 18.97) (5). Another study describes 4 strains that survived disinfection at 80 °C/3 min (A_0 = 180) (6). "Survived" in this case means that from a baseline population of around 10^8 bacteria, 1 to 3 bacteria had survived (this corresponds to an RF of almost 8 log levels). However, no isolate survived exposure at 75 °C/10 min (A_0 = 190). Finally, one publication reported on 3 *E. faecium* isolates with an RF < 5 log levels (between 3 and 4) at 80 °C/1 min (A_0 = 60) as well as on one isolate with an RF < 5 log levels at 80 °C/3 min (A_0 = 180) (7). The exact RF value in the latter case was 4.79 log levels. But all isolates were killed at 80 °C/10 min (A_0 = 600), (RF > 8 log levels).

In addition to heat-resistant bacteria there are also heat-resistant viruses, with the hepatitis B virus being the most important as far as infection control is concerned.

The approach taken to thermal disinfection in washer-disinfectors in the German-speaking countries right up till the present day is characterised by the virtually sacrosanct conditions of 93 °C/10 min (A_0 = 11972). The 93 °C value was originally chosen in order to ensure that one would reach 90 °C (A_0 = 6000) in the washer-disinfectors used at that time which were not so easy to regulate. Without elaborating on the entire history of these conditions formulated by the former German Federal Health Office (BGA, now the RKI), it can be stated that the heat-resistance profile of HBV was a vital consideration when specifying these conditions. It appears that, in turn, the study conducted by a Japanese research group has played an important role. This study demonstrated that human blood plasma with an HBV titre of 10^8 infective doses per ml could no longer cause infection in chimpanzees after heat treatment for 2 min at 98 °C (A_0 = 7571) (8). However, this publication does not produce any data on the conditions that serve to identify the transition between from the infective to the non-infective setting. Does 2 min at 98 °C mean an x-fold overkill or that complete inactivation was just about achieved?

More information can be provided by the data on pasteurisation experiments conducted on blood products contaminated with HBV as well as by the tests carried out with the bovine parvovirus, which is endowed with a similar resistance profile to moist heat as that evidenced by HBV; this is therefore now being used as a surrogate virus for efficacy testing of thermal inactivation processes for HBV. In the pasteurisation tests with HBV a titre reduction of 4-5 log levels at 60 °C/10 h (A_0 = 360*) were observed (9,10). The tests with the parvovirus achieved a 4 log reduction under similar conditions, and at 60 °C/28 h (A_0 = 1008*) a reduction of 7 log levels (11) (Fig. 1). But the tests with the parvovirus also demonstrated that inactivation was achieved more rapidly in distilled water (simulating the conditions prevailing for thermal disinfection) than in plasma.

Selection of A_0 Values in Everyday Practice

The standard prEN ISO 15883-1 defines disinfection as follows: "Reduction of the number of living microorganisms on a device to a pre-specified level, which is tailored to the intended subsequent handling or use of the device." At least 5, sometimes 4 log level RF values (viruses, prEN14476) are stipulated for chemical disinfectants, depending on the microbial species involved. What titre reduction should be required for thermal disinfection processes?

prEN 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, etc., (Part 2) with an A_0 = 600.

*) The A_0 equation is actually valid only for temperatures ≥ 65 °C, since the z value can fluctuate greatly at lower values. But this does not seem to be the case for HBV at 60 °C. Pasteurisation of plasma at 60 °C/10 h is a standard method. Moreover, z = 10 °C provides a safety reserve.

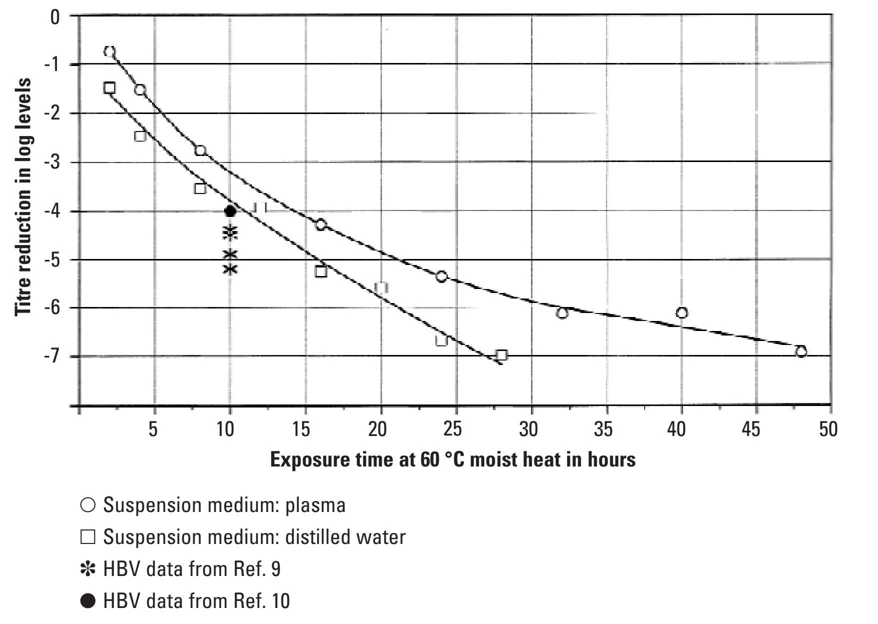

Fig. 1 (from Ref. 11) Reduction of infective units of bovine parvovirus (BPV) and hepatitis B virus (HBV) through pasteurisation at 60 °C

Furthermore, the standard stipulates that a washer-disinfector must be capable of conducting disinfection with A_0 = 3000, but no application is defined for this.

Are these requirements as enshrined in the standard sufficient, in view of existing data on thermal inactivation processes? The answer is yes and no as far as the human waste containers are concerned, and yes in the case of surgical instruments, etc. That faeces have a very high microbial concentration is a generally known fact, and also that there are antibiotic-resistant enterococci. The *E. faecium* isolates, with an RF < 5 log levels at 80 °C/1 min or 80 °C/3 min, were resistant to vancomycin (7). An A_0 = 60 for this application could thus be queried by all means. But it should not be forgotten that a "bedpan washer", too, is performs two cleaning steps before disinfection, thus reducing the microbial titre already before disinfection.

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. If the time needed for an A_0 = 600 is calculated on the basis of the kill kinetics for the parvovirus in Fig. 1, this amounts to 16.67 hours or to a titre reduction between 5 and 6 log levels, i.e. more than that stipulated for chemical disinfection. While the virus titre for an HBV carrier can be very high, up to 10^9/ml, the instruments must always be cleaned prior to disinfection. Already a titre reduction of approx. 4 log levels (12), ideally even of more than 5 log levels, can be expected from the cleaning step (13). Together, this confers an adequate level of safety so that the processing personnel can handle the instruments without having to fear any risks. In any case, all critical instruments are also sterilised before being used on patients. Routine disinfection with A_0 = 3000 is therefore not justified and, correctly, the standard prEN ISO 15883 makes no provision for it. But as a compromise, the following approach could be adopted: all instruments being sterilised 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 sterilisation 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. ✻

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