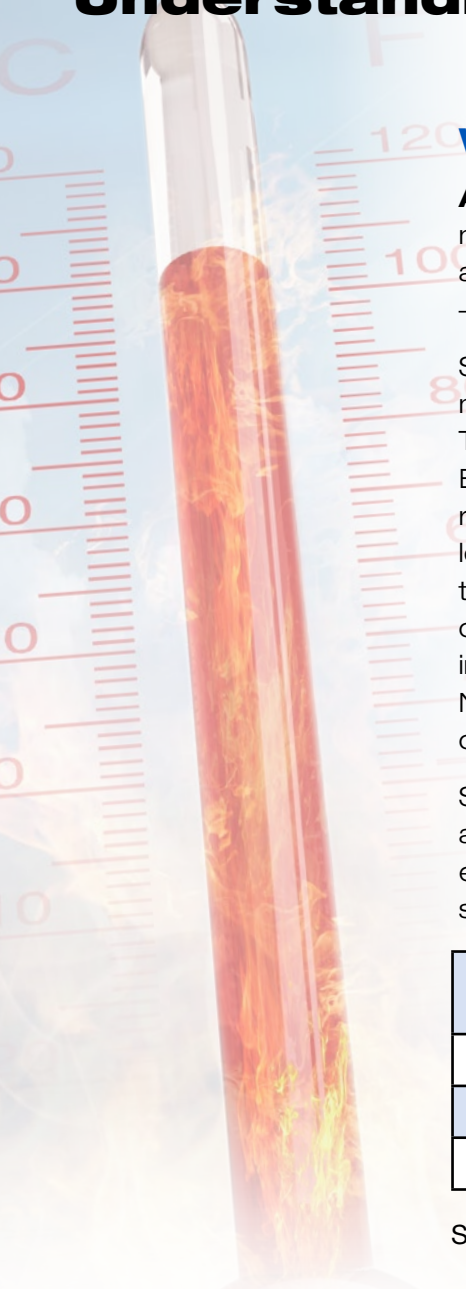
Understanding Thermal Disinfection Using A_o



What is A_o?

A_o is an expression of the **expended energy** (time/temperature) needed for the disinfection process in a washer/disinfector to achieve a desired level of kill. Another way to express this is "area-under-the-curve" – **the amount of energy that was applied to a load.**

Specifically, **A_o** is the time required to achieve a specified log reduction of microorganisms based on the temperature of the thermal disinfection cycle. The **A_o** concept is used mainly outside the United States and is described by EN (European Norm) ISO 15883. The number following the **A_o** symbol represents the number of seconds needed at 80°C/176°F to achieve the level of disinfection specified by the particular **A_o** designation. According to EN ISO 15883, the minimum disinfection requirement for human waste containers is **A_o** 60 and the mimumum disinfection requirement for surgical instruments is **A_o** 600. No application for **A_o** 3000 has yet been established. Nevertheless, EN ISO 15883 specifies that a washer/disinfector must be capable of achieving **A_o** 3000.

Since the **A_o** represents a combination of time and temperature, there are different ways to achieve specific levels of **A_o** disinfection. **A_o** 600, for example, may be achieved using the time and temperature combinations seen below:

A_o	TEMP °F/°C	TIME [SEC]	TIME [MIN]
600	176/80	600	10
600	194/90	60	1
600	199/93	30	0.5

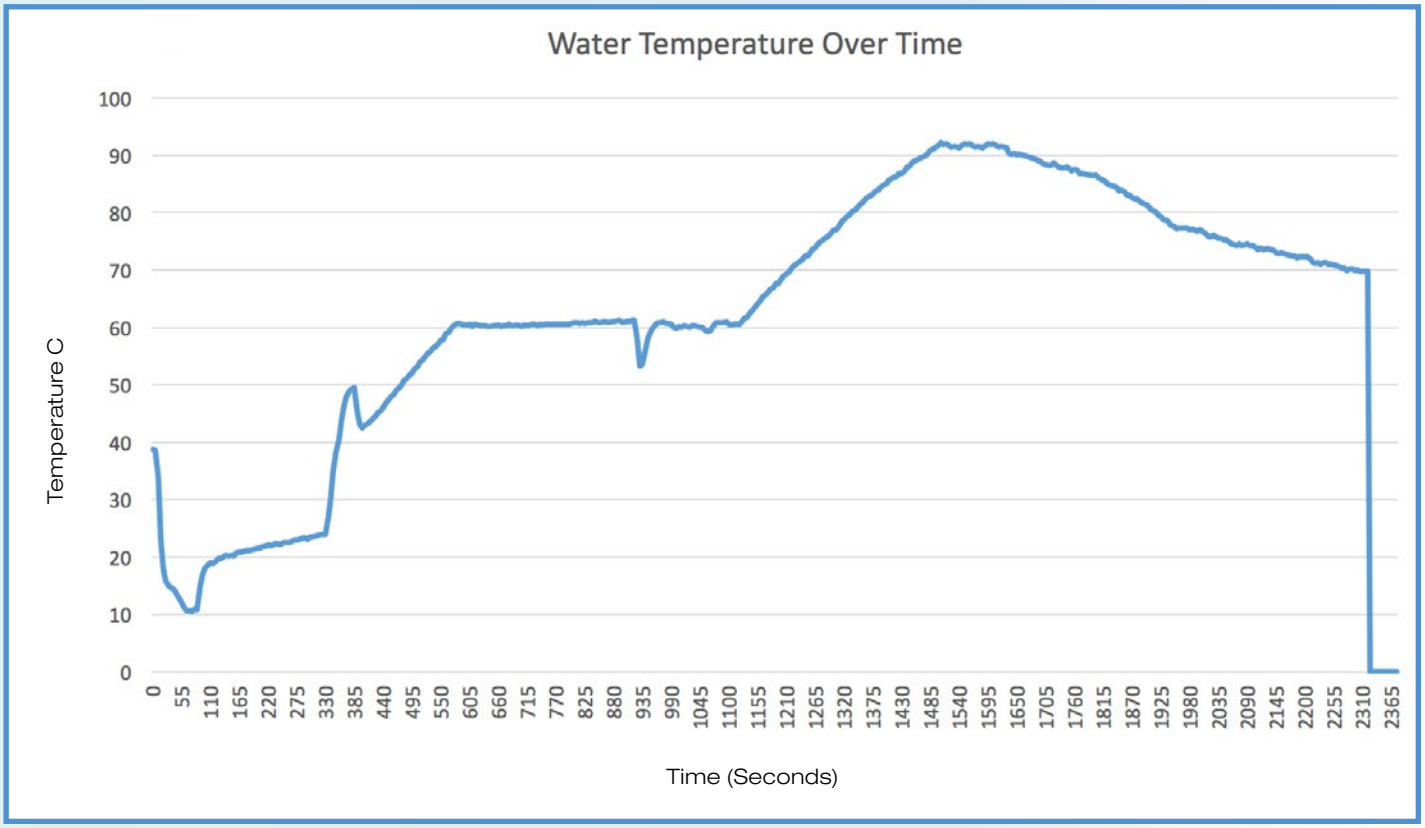
Source: ISO 15883-1; annex B

References:

1. Rosenberg U, Thermal Disinfection – The A_0 Concept and the Biological Background, Central Service, Vol. 11, 2003
2. Rohm-Rodowald E, Jakimiak B, Chojecka A, Wiercinska O, Ziemba B, Kanclerski K, Recommendations for Thermal Disinfection Based on the Concept According to EN ISO 15883, Przegl Epidemiol, 2013;67:787-690
3. A_0 Made Simple, STERIS Corporation 2008
4. Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors; Guidance for the Medical Device Industry and FDA Review Staff http://www.fda.gov/RegulatoryInformation/Guidances/ucm073357.htm

What are the benefits of A_0?

1. **Communication:**
   - **a.** **A_0** refers to a specific disinfection level, regardless of which temperature was used or for how long.
   - **b.** The usage of **A_0** allows the direct comparison of disinfection levels
2. **Time Savings:**
   - **a.** Thermal disinfection begins to take place at 149° F (65° C) which is below the time/temperature plateau for a typical washer/disinfector cycle. **A_0** takes the heating time during which thermal disinfection is taking place into account. Often the **A_0** 600 can be obtained shortly after reaching the plateau.



NOTE: Countries using **A_0** continue to debate the benefits of **A_0** 3000 or higher. The incremental gain in microbes killed going from **A_0** 600 to **A_0** 3000, depending on the specific organisms or strains, for example, could easily be zero. As a result, a number of experts have argued that routine disinfection using **A_0** 3000 is not justified and that the time saved by using **A_0** 600 versus **A_0** 3000 can be put toward more cleaning and increased throughput. In other words, **A_0** = 3000 is considered "doing-too-much" and it would be more useful to spend the extra time required to achieve **A_0** 3000 on cleaning instead.[1, 2]

What are the differences in requirements for thermal disinfection in the United States versus Europe?

UNITED STATES

FDA does not recognize **A_0**, but does stipulate that any washer/disinfector sold in the United States claiming thermal disinfection for reusable medical devices must be capable of achieving intermediate level disinfection.

Intermediate level disinfection is defined by FDA as a 6 log reduction of a mixed suspension of vegetative organisms and a 3 log reduction of an appropriate thermophilic mycobacterium species.[3]

All STERIS washer/disinfectors currently being sold for disinfection of reusable medical devices meet or exceed FDA requirements for intermediate level disinfection **and** are EN ISO 15883 compliant.

EUROPE

Europe follows EN ISO 15883, which stipulates that:

- **A_0** 60 is a minimum requirement for human waste containers
- **A_0** 600 is a minimum requirement for disinfection of surgical instruments.
- Washer/disinfectors must be capable of achieving **A_0** 3000, but does not define an application for this.

National requirements can vary, but most hospitals in Europe target disinfection above the minimum requirement specified in EN ISO 15883 (e.g. BGA or Bundesgesundheitsamt in Germany, now RKI, specifies 93 °C/ 200°F for 10 minutes which would yield **A_0** 12,000)

Summary: In the United States, the responsibility for ensuring compliance with thermal disinfection requirements rests with the manufacturer. In Europe, the manager of the CSSD may decide in light of professional advice, to program the washer/disinfector to perform the appropriate cycle on a given load.

FDA specifies a minimum log reduction requirement. Manufacturers must be able to produce documentation to prove their equipment meets this requirement. EN ISO 15883 requires thermal mapping documentation that a specific **A_0** value was achieved.

STERIS: Meeting and exceeding all accepted standards and requirements globally

STERIS PLC is a **global** company and, as such, its washer/disinfectors comply with and exceed all accepted standards and requirements for thermal disinfection worldwide. All STERIS washer/disinfector cycles can be set to run using a time/temperature-based model (**A_0** 600, 3000, 12000) if desired. Regardless of a country's specific thermal disinfection requirement, however, the unique efficacy profile of STERIS washer/disinfectors delivers Customers the **fastest** cycle time of any washer/disinfectors currently available.

STERIS

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Document # M4383EN.2016-11 Rev. A