Letters to the Editor

Flash Sterilization

To the Editor:

In a recent issue of *Infection Control* (now *Infection Control and Hospital Epidemiology*) an article appeared entitled "An Evaluation of Three Biological Indicator Systems in Flash Sterilization."[1] The authors presented data indicating that among three biological indicator (Bl) systems investigated (3M Attest® #1261, AMSCO Proof Flash™, and Castle Tec Test®) the Attest Flash monitored a three-minute flash cycle more satisfactorily than the other two. The authors have based their conclusion on several factors that we believe were presented in both a commercial and an erroneous manner.

Our first point of contention concerns an appropriate flash Bl population level. The authors cite[2] the population level of contaminated instruments to be approximately 10^3 microorganisms; however, they fail to mention that 96% of the instruments, following treatment in an instrument washer or immersion in a disinfectant, were stated to carry less than 10^2. Both of these populations consisted largely of microorganisms in a vegetative state[2] having no significant resistance to steam at 270°F.[3(pp74-87)] The performance of a Bl is a result of its design, the inherent resistance of its bacterial spores, and its spore population. This population level is tailored to provide the appropriate resistance for the process being monitored. The Proof Flash Bl is inoculated with 10^2 spores of *Bacillus stearothermophilus*, ATCC 12980, a strain different from that used in Attest. Repeated sterilizer testing has shown that this population (of this strain) yields appropriate, not excessive, resistance for a flash Bl. By appropriate we mean simulating the performance of a spore strip, which for years has served as the accepted standard for sterilization monitoring.[3(pp494-499),4]

BIOLOGICAL INDICATOR FLASH DATA*

	30 Sec.	1 Min.	2 Min.	3 Min.	4 Min.
Attest	1001100	1001100	1001100	31100	2/100
Proof Flash	1001100	95/100	34/100	0/100	0/100
Spordi	1001100	0/100	0/100	0/100	0/100

*No. Bls positive/no. Bls exposed.

This leads to our next point of contention: Bl resistance. The data reported in the article do not agree with data previously generated[5] and with those recently generated in an AMSCO gravity displacement sterilizer in the OR area of a municipal hospital (see Table). Proof Flash met its resistance claims, demonstrating a slightly higher resistance than the Spordi Biological Indicators (a spore strip). The Attest flash Bl was far too resistant, resulting in false positive results. A major reason for the discrepancy between the data submitted here and those in the article is the difference in sterilizer "come-up time." The article cites a come-up time of 1 minute 31 seconds; this excessive time will result in additional Bl kill. As a sterilizer manufacturer, we are aware that many 16 × 16 or 20 × 20 hospital sterilizers have a 270°F flash come-up time of less than 60 seconds; Proof Flash data were generated with a 50- to 65-second come-up time.

A third point of disagreement is Bl outgrowth rate. The Food and Drug Administration (FDA) issued a guideline in 1985 for validation of biological indicator incubation time.[6] This guideline was not followed by the authors since the appropriate number of Bls was not tested, the required partial survival data was not generated for the Attest Bl, all daily readings were not reported, and the Attest Bl was not incubated for seven days. The metabolic and reproductive rate of a thermophilic organism such as *B stearothermophilus* makes it very difficult to accept as credible the one-minute exposure outgrowth data reported in the publication for Proof Flash. A 24-hour incubation period has been validated for the Proof Flash Bl in accordance with the FDA guideline.

The last point of contention involves the attack on Proof Flash user compatibility. Proof Flash has on its label a bar indicating how far the cap should be depressed to affect media release and proper seal. A Proof Flash crusher is also available, as indicated in product instructions, to assure proper Bl activation, preventing media leakage or evaporation due to improperly seated caps. A slightly lighter Proof Flash Media color noted immediately following exposure at 270°F is restored to the original purple during the cooling process and is only more apparent in the Proof Flash unit because of its larger, see-through vial. Browning of the Proof Flash media will only occur following exposure to excessive (>280°F) sterilizer temperatures.

In closing, we believe that the article on flash sterilization is totally a commercial endorsement for 3M's Attest, not a true scientific appraisal. Careful attention should have been given to "treat all Bls equally," to investigate and follow established Bl guidelines, and to make sound recommendations based upon accepted standards.

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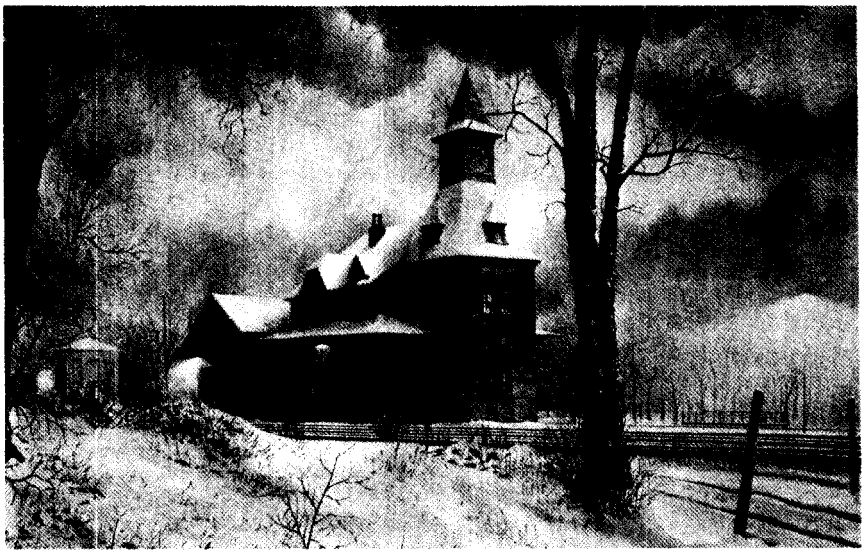

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Ms. Kotilainen and Dr. Gantz reply to Dr. Gammon and Ms. Boris.

Thank you for the opportunity to respond to the interesting, if somewhat biased, letter from Dr. Richard Gammon and Ms. Cynthia Boris of AMSCO Medical Products. Our response to each of their four concerns follows.

Their first point seems insignificant given that the difference between 10^2 microorganisms and 10^3 microorganisms is only 1 log. However, we will agree that most organisms encountered on instruments could be expected to be vegetative without any significant steam resistance. We certainly agree that spore strips have been the gold standard for cycle monitoring. Published standards from the United States Pharmacopeia (USP), however, state that BIs for steam sterilization should contain 10^4 to 10^9 spores per strip of Bacillus *stearothermophilus* Standards for flash sterilization BIs are not published, but USP does state that when another spore concentration is used and subjected to 121 ± 0.5°C, the D value should be between 1.3 and 1.9 minutes. As manufacturers do not routinely publish D values, the consumer is left wondering why Proof Flash contains 10^7 spores versus 10^5 spores. Interestingly, Proof Plus contains 10^4 spores.

We do not believe that the come-up time was excessive. In our experience with other flash units at other facilities the average come-up time is 1 minute 15 seconds. However, as Perkins and others have stated, a true sterilization-capable cycle is not achieved until the proper temperature and pressure has been met for the required time. We do not feel that users should include come-up time as part of an appropriate length cycle.

However, for the sake of discussion, even if come-up time is included in the length of the cycle, at the one-minute exposure level (total cycle length 2 minutes, 31 seconds) in run #1, only 44% of the Proof Flash became positive by seven days, and more importantly for the hospital user, 8.3% were positive by 48 hours. This slow outgrowth was also reflected in one positive control which required 36 hours for a media color change. At the time of the study, the Proof Flash product insert stated a "high degree of readout reliability at 48 hours of incubating" and suggested that for additional confidence, incubation could be extended to seven days.

The FDA guideline, which uses a sample size of 100, is intended to be used as suggested reference for industry. However, for the number of samples tested and the results generated, the data cannot be interpreted as due to chance alone. Daily readings were taken for each RI tested; these results added little to the published study and were not included on the tables because of their cluttering effect.

The Attest BI was not incubated in this study for seven days as we were following the manufacturer's instructions. However, since this time, we have repeated this evaluation for additional lots of Attest as well as Proof Flash. We found no outgrowth of Attest after 48 hours when held up to seven days.

We recognize AMSCO's concerns over user incompatibility. We did read the package inserts and did use the suggested crusher. The experiment was repeated because of our wish to give Proof Flash a fair evaluation. As stated in the article in the second run, all Proof Flash were properly cracked, sealed, and seated after a fair amount of practice. Evaporation of media before seven days was still observed.

The information about browning of media when exposed to temperatures exceeding 280°F is interesting. As a recording thermometer was threaded through the door gasket and temperature continuously monitored, we can assure you that at no time did the temperature exceed 275°C for any run. When we noted discolored media, we meant that it was brown, not light purple, on removal from the sterilizer and that it did not return to its original color.

In summary, given the conditions under which flash sterilization is usually performed, commonly without optimal preparation of the materials and user intervention of the cycle, our facility prefers not only a more resistant biological indicator but also one with a narrower survive/kill ratio. As we do not dismiss our occasional positive spore tests as nuisances or flukes and by monitoring our sterilizers daily with two BIs for each unit, we have been able to detect minor inconsistencies in cycle performance, such as poor steam quality or aging door gaskets, before a major failure occurs. In flash sterilization, a major failure can not be acted upon either because the instruments have already been used or a patient, often under anesthesia, waits for instruments to be reprocessed in a functioning sterilizer. Proof Flash was an unsatisfactory indicator system using standard methodology.

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