Vesley, but rather only to question their efficacy predicated on a test pack that may not be appropriate for validating the operating efficiency of the sterilizer, let alone the efficacy of a device used in a vitally critical application.

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The authors reply

Dr. Belkin's letter raises an important issue relative to the simulation of in-use conditions in a steam sterilizer using the standard AAMI test pack. However, our purpose was not to validate the performance of the sterilizer, but to evaluate the new rapid readout indicator developed by 3M. Indeed, a denser and larger test pack could result in additional positive indicators at the times we tested, and we would hope that AAMI will continue to seek a standard pack that realistically simulates the actual in-use conditions of these sterilizers. We do not feel qualified to pass judgment on that issue at this time.

Using the currently recommended AAMI test pack, we believe that we have demonstrated conclusively that the new biological indicator (BI) is significantly more sensitive in detecting failures of the sterilizer to maintain the prescribed time and temperature parameters than any other indicator on the market and that it can do so in a much shorter time. It was our observation that the vacuum-assisted sterilizer that we used in our studies rendered all of the tested BIs negative (killed all the spores) in a considerably shorter time than the recommended cycle. Indeed, we had some negative BIs even at zero time. Perhaps this would compensate for the lesser density of the test pack.

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FDA Labeling Requirements for Disinfection of Endoscopes: A Counterpoint

To the Editor:

I would like to offer the following commentary in response to Dr. William Rutala's article, "FDA Label Requirements for Disinfection of Endoscopes: A Counterpoint."[1]

Drs. Rutala and Weber suggest that "The FDA should modify the label of the liquid germicide that requires a 45-minute immersion at 25°C to support a high-level disinfection claim. Their recommendation is for the label to state, "if cleaning is accomplished using a standard cleaning protocol, then a 20-minute immersion at 20°C will be sufficient." Their conclusions are based on the fact that investigators found that cleaning alone reduces the microbial load enough to allow such a reduction in time and temperature. No doubt, when flexible endoscopes are properly cleaned, as would be the case when an investigation or research project is undertaken, the findings would be verified.

But—and it is a big but—under less controlled conditions, such as in a busy hospital or private practice, cleaning is much less adequate. This was demonstrated clearly in an article published in 1992 in the *American Journal of Medicine*.[2] The authors draw very different conclusions from their review of actual processing of endoscopes. Through interviews and observation, they found fundamental errors in the cleaning. They also found that 23.9% of bacterial cultures obtained from the internal channels grew ⩾100,000 colonies after cleaning and disinfection of the scopes. This occurred when personnel knew they were being interviewed and observed; infection control personnel can only guess what happens when no one is checking.

But, even when personnel process these instruments conscientiously and to the best of their ability, they may not achieve the cleanliness they strive for; the structure and materials of the endoscopes hinder efforts for effective cleaning. These conclusions and concerns are voiced in the APIC Guideline for Infection Prevention and Control in Flexible Endoscopy.[3,4]

I oppose having dual label instructions for disinfection, one for instruments that are adequately cleaned and another when adequate cleaning is not achieved. First of all, no one would recognize or want to admit, even to themselves, that they are not adequately doing what they are supposed to be doing. And second, when they see the 20-minute, 20°C instructions, they may read no further.

There is a third reason I oppose such labeling. If the manufacturer feels 45 minutes' immersion at 25°C is necessary, we should not reduce the time. If anything, the time should be increased to allow for errors. And up to now, no one has yet explained to my satisfaction why the 25°C temperature is listed by the manufacturer, and yet 20°C is recommended by Drs. Rutala and Weber. I hope readers will remember, from articles I have published