Box B. ***Eliminates exposure to vapors?*** This evaluation states that the Reliance EPS "eliminates personnel exposure to toxic LCG (liquid chemical germicide) agents and fumes."[1] Such a finding, if true, would be an advantage. But, this evaluation appears not to have performed the necessary air-sampling tests to conclude that in the surrounding environment the disinfectant's fumes were *eliminated*–as opposed to *reduced*, which is both the more common attribute of AERs and, ironically, more consistent with its manufacturer's advertised claims.[30,41] Without having performed these air-sampling tests, this evaluation's conclusion that the Reliance EPS "eliminates" its disinfectant's fumes would be in doubt. Similarly, this evaluation does not provide any references to support its conclusion that "most" facilities use Olympus's or Fujinon's GI endoscopes—not Pentax's contraindicated endoscopes. ●

✓ **The REFERENCES to this article are available at:**
www.myendosite.com/htmlsite/2008/refs111208.pdf

Box C. ***Self-decontamination?*** The FDA requires manufacturers of AERs to demonstrate that the internal design of their AERs are not prone to bacterial colonization. This is a necessary requirement, because the flawed internal designs of AERs have been linked to bacterial colonization and both patient morbidity and mortality.[31,44] An important aim of this evaluation, therefore, was to determine whether the Reliance EPS "possesses any design flaws that could lead to reprocessing failures." This aim can often be achieved by performing tests that include artificially contaminating an AER's internal surfaces with waterborne bacteria, if not biofilms, and verifying the proliferation and colonization of these bacteria. A determination that the AER's internal surfaces are no longer colonized with these bacteria after operation of the AER's "self-decontamination" cycle typically indicates this cycle's effectiveness.

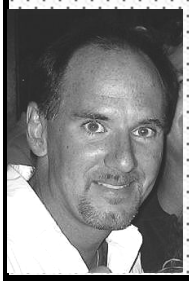
Nevertheless, although it describes some details about the Reliance EPS's two automated "self-decontamination" cycles, this evaluation does not provide data or results to demonstrate that the effectiveness and safety of either cycle was evaluated. Instead, this evaluation provides the manufacturer's published specifications for these two cycles. Not performing the necessary tests to evaluate the Reliance EPS's two "self-decontamination" cycles—despite rating this AER *preferred* and "strongly" recommending its use (for compatible endoscopes)—is confusing and suggests that this evaluation may have confused a manufacturer's claim with independently acquired, evidence-based data. (See: **Box A**, **Box B**; also, refer to this newsletter's main article). ●

Box D. ***Cost considerations:*** This evaluation states that the list price of the Reliance EPS is $38,000, which, according to this evaluation, is "about $6000 to $7000 more" expensive than *traditional AERs*.[1] Further, this evaluation acknowledges that the cost of the Reliance EPS's single-use disinfectant (per cycle) is $8.50 (and $10.50 "per cycle for all consumables").[1] As noted by ECRI Institute in another of its published evaluations (but not disclosed in this one),[42] the cost associated with using 2% glutaraldehyde (per cycle) in the disfavored *traditional AERs* is $1.75—or almost 80% less.

Paying a higher price for a preferred product may be prudent, but doing so would require that some circumspect performance and safety criteria be clearly satisfied. Although it lists both the higher initial and per-cycle costs associated with the Reliance EPS as a *con*, this evaluation does not justify these higher costs by citing any published studies, or performing tests and including any simulated in-use or clinical performance data, demonstrating that, compared to the *traditional AERs*, the Reliance EPS more effectively achieves high-level disinfection. Arguably placing insufficient weight on cost considerations, this evaluation's awarding of the rating "preferred" to a device that is significantly more expensive, but for which data showing that it improves clinical outcomes (i.e., reduces the risk of infections) have not been published, is another of this evaluation's confusing qualities. ●

✓ **Wishing you a Happy Holiday and New Year.**

Thank you for your interest in this newsletter. *I have addressed each issue and topic to the best of my ability. Respectfully, Lawrence F. Muscarella, Ph.D.*
Please direct all correspondence to:



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