The Difference Between Chemical Integrators and Biological Indicators
Under “acceptable” conditions for steam sterilization, the integrators compared reasonably well with the biological indicators. However, the integrators were not able to consistently detect the failure conditions of superheated steam and incomplete air removal as did the biological indicators in all cases.

Test Methodology:
250°F Superheated steam using a prevacuum cycle with an 8-minute exposure in a BIER Vessel (% positive for biological indicators and % reject for chemical integrators)
ABSTRACT

The study, published in the American Journal of Infection Control, demonstrates that **chemical integrators (CIs) and biological indicators (BIs) are not equivalent** in the role of identifying sterilization failures.

CIs provide immediate valuable information about specific parameters of the sterilization process such as time, temperature and steam quality. **CIs are designed to test certain conditions within a specified range**, but do not reflect the complete range of processing conditions.

While Class 5 chemical indicators, termed “integrating indicators,” react to multiple parameters, the study shows that **they can fail to detect sterilization failures**.

Chemical integrators **are not equivalent to** biological indicators. Only biological indicators demonstrate the ability of a steam process to kill microbes.
“Chemical integrators can never be equivalent because a biological indicator shows spores were actually killed. Chemical indicators do not.”

“Biological indicators are the only monitoring devices that automatically measure every factor that could possibly affect spore destruction.”

— Dr. Donald Vesley, University of Minnesota

“Chemical indicators could be used in conjunction with biological indicators, but should not replace them, because of inadequacies at marginal sterilization times and because only a biological indicator consisting of resistant spores can measure the microbial killing power of the sterilization process.”

— Dr. William Rutalla, University of North Carolina. *Infection Control and Hospital Epidemiology*, Vol. 14, 1993

“The “pass” response of a CI does not prove that the item monitored by the indicator is sterile. The use of CIs is part of an effective quality assurance program; they should be used in conjunction with physical monitors and BIs to demonstrate the efficacy of the sterilization process.”

— ANSI/AAMI ST46, 2002

“The only currently accepted system capable of integrating all physical parameters responsible for lethality is a BI... The BI is the only tool that will accurately integrate the combined lethal parameters within the load... More weight must be given to biological results because all critical parameters cannot be measured by physical means.”


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