Biological Indicators play an important role in the monitoring of sterilizers, along with physical and chemical indicators. However, only BIs contain live spores that directly measure the lethality of a sterilization cycle. For this reason, they’re considered the “gold standard” in sterility assurance.

Centers for Disease Control & Prevention

“Biological indicators are the most accepted method for monitoring the sterilization process because they access it directly by killing highly resistant microorganisms, rather than merely testing the physical and chemical conditions necessary for sterilization. Because spores used in BIs are more resistant and present in greater numbers than the common microbial contaminants found on patient-care equipment, an inactivated BI indicates other potential pathogens in the load have been killed.”

Centers for Disease Control & Prevention
Biological Indicators

Conventional BIs consist of spores in or on a carrier, sometimes accompanied by culture medium (as in the case of SCBIs). They contain a large number of highly resistant bacterial spores that are non-pathogenic, and therefore safe for health care workers to work with.

Conventional BIs must be incubated until it’s determined whether or not spores grow (as indicated by a visual color change in the growth media). Depending on the BI supplier, there can be a different incubation time/temperature for BIs containing the same organism.

Some types of BIs contain spores with an enzyme early readout capability. “An active enzyme is impregnated on a carrier strip located between the walls of the outer and inner containers, and a substrate that reacts with the active enzyme is contained within the sealed inner tube. The enzyme system gives a rapid indication of the effectiveness of a sterilization cycle, which is then confirmed by measurement of spore outgrowth over a longer period of time.”

Patent 6,897,059
Biological Indicators

This brings up an important question! Do users confirm spore outgrowth with continued incubation, or just rely on the 1 hour and 3 hour “enzyme” early readout?

The 290 Auto-reader is designed to allow for further incubation of the 1291 and/or 1292 RRBI for a final negative, visual pH color change of the growth media at 24 hrs for 1291 and 48 hrs for 1292.*

*Auto-reader manual

Biological Indicators

The Department of Veterans Affairs says…

“A rapid readout biological may be used in the pre-vac steam sterilizers with wrapped supplies. A reading may be taken at 3 hours, and the results must be recorded. However, the biological must remain incubated, be visibly read, and the results must be recorded at 48 hrs.

No biological reading will be taken in less than 3 hours. Rapid readout biological monitors are not to be used in flash sterilizers.”

Biological Indicators

“When a positive biological test result is obtained, the biological indicator will be immediately submitted to the microbiology laboratory for a presumptive organism identification. This helps to determine if the living microorganism is the indicator test microorganism (indicating inadequate sterilization conditions) or if an accidental contaminant could have been introduced after the load was removed from the sterilizer.”

VA DIRECTIVE 7176
Biological Indicators

ANSI/AAMI Standard says...
“Periodic verification of the early readout with spore growth should be performed in accordance with the manufacturer’s instructions and facility policy and procedures. For this verification, the BI with enzyme-based early-readout capability can be further incubated to demonstrate spore growth by a visible color change. In the event of sterilization process failure, the sterilizer manufacturer may recommend additional biological testing to verify results.”

Biological Indicators

“For positive BIs, the microbiology laboratory should perform a presumptive identification according to the BI manufacturer’s instructions to determine whether the recovered microorganism is indeed the test microorganism that was on the spore strip or is a laboratory contaminant.”

ANSI/AAMI ST79
AORN Recommended Practices

Chemical Indicators

Class 1
Process Indicators are intended for use as an external indicator to distinguish between processed and unprocessed items.
Chemical Indicators

Class 2
Specific Test Indicators are Bowie-Dick type indicators for use with air removal testing.

Two Options:
1) Buy a commercial test pack (single use or reusable),
2) Make your own test pack using freshly laundered towels (10x10x11-12") with an indicator sheet placed in the center and single wrapped.

Chemical Indicators

Class B prevacuum type steam sterilizers (small or large) should be tested daily with a Bowie-Dick test for proper air removal.

This is usually done in the morning, before the first processed load.

Chemical Indicators

The Bowie-Dick test is placed over the drain in empty chamber and run at 273°F for 3.5 or 4 minutes. Dry time is optional and AAMI standards now recommend placing the test on a cart (large sterilizers) if a cart is routinely used to process loads.

The indicator inside the test pack should show a uniform color change to pass.
Chemical Indicators

Class 3
Single Parameter
Chemical Indicators

These are designed to react to one parameter of the sterilization process, to indicate exposure at a stated value.

Indicator melts when reaching a specific temperature, e.g. 270°F.

Chemical Indicators

Class 4
Multi-Parameter indicators designed to react to two (2) or more critical parameters, to indicate exposure at stated values.

Special Note:
Some companies claim “multi-parameter” but then reference Class 1 which are only process indicators. Multi-parameter indicators must comply to Class 4 specifications outlined by ISO 11140-1 as tested in a laboratory resistometer.

Chemical Indicators

Class 5
Integrating indicators react to all critical parameters of the sterilization process over a specified range of sterilization cycles and their performance correlates to BI performance as stated on their labeling.
The new ANSI/AAMI/ISO standard 11140-1 requires very rigid criteria for Class 5 chemical indicators:

- Stated values must correlate to the results of the BI at 250°F, 275°F and a minimum of one point between,
- Must have a stated value at 250°F that is greater than 16.5 minutes, and
- Must pass dry heat test showing it does not reach its endpoint in 30 minutes at 280°F.

The stated goal of the Class 5 indicator manufacturers is to design a product that will provide as much information as a biological indicator. Class 5 chemical indicators benefit users as they do not require incubation and offer immediate results.

Class 6 indicators are cycle verification indicators that confirm the presence or absence of specific time and temperature parameters during a cycle, and integrate all the critical parameters of the cycle, e.g. temperature, saturated steam and exposure time.

Class 6 indicators are currently only available for steam processes (standard cycles). AAMI and AORN has not made any recommendations as to their benefit or use, as of yet.
Chemical Indicators

Class 6 chemical indicators are “cycle specific” in that different cycles require a different indicator.

- They can be comparable to a BI at only ONE time/temperature condition.
- They can not be used for all steam cycles.
- They are used in Europe where they have cycles that differ than the U.S. and in many cases, do not use biological indicators as the “gold standard”.

Time/Temperature Response Comparison

THANK YOU!

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## References

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Centers for Disease Control and Prevention  
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