

Steam Chemical Indicator Classes Defined:

Class	ANSI/AAMI/ISO 11140-1: 2005 Definition*	Practical Application
Class 1: Process Indicators	“Process indicators are intended for use with individual units, (e.g., packs, containers) to indicate that the unit has been directly exposed to the sterilization process and to distinguish between processed and unprocessed units. They shall be designed to react to one or more of the critical process variables.”	Indicator tapes, indicator labels, and load cards are examples of externally visible Chemical Indicators that are Process Indicators used for exposure control.
Class 2: Indicators for use in Specific Tests	“Class 2 indicators are intended for use in specific test procedures as defined in relevant sterilizer/sterilization standards.”	Bowie-Dick type tests are specific tests used for equipment control to evaluate the sterilizer performance.
Class 3: Single Variable Indicators	“A single variable indicator shall be designed to react to one of the critical variables and is intended to indicate exposure to a sterilization process at a stated value (SV) of the chosen variable.”	An example of a Single Variable Indicator is a temperature tube that contains a chemical pellet that melts at a specific temperature. Single variable indicators may be used for pack control monitoring but would not provide as much information as a Class 4 or Class 5 Chemical Indicator. Single Variable Indicators may also be used for exposure control monitoring. This temperature tube would be used to determine that a specific temperature was reached at a specific location in the sterilizer chamber.
Class 4: Multi-variable Indicators	“A multi-variable indicator shall be designed to react to two or more of the critical variables and is intended to indicate exposure to a sterilization cycle at SVs of the chosen variable.”	Multi-variable Chemical Indicators are used for pack control. These internal Chemical Indicators are usually paper strips printed with a Chemical Indicator.
Class 5: Integrating Indicators	“Integrating indicators shall be designed to react to all critical variables. The SVs are generated to be equivalent to, or exceed the performance requirements given in the ISO 11138 series for BIs.”	Integrating Indicators are the most accurate of the internal Chemical Indicators. Integrating Indicators are used for pack control monitoring. They can also be used as an additional monitoring tool to release loads that do not contain implants. For this additional monitoring the Class 5 Integrating Indicator must be used in the appropriate challenge test pack or Process Challenge Device (PCD). These indicators must now have SVs at 121°C/250°F, 135°C/276°F, and at least one more temperature in between. Also, the SV at 121°C MUST be greater than 16.5 minutes to ensure performance is comparable to BIs in saturated steam.
Class 6: Emulating Indicators	“Emulating indicators are cycle verification indicators which shall be designed to react to all critical variables for specified sterilization cycles. The SVs are generated from the critical variables of the specified sterilization process.”	Emulating Indicators can be used as internal Chemical Indicators for pack control. Emulating Indicators are specified for specific sterilization cycles which means an end user will need to inventory a different Class 6 Emulating Indicator for each sterilization cycle time and temperature (i.e., 3 min, 5 min, 10 min, 18 min, 40 min, etc.) run in the facility. The response of a Class 6 Emulating Indicator does not necessarily correlate to a Biological Indicator so the indicator cannot be used as an additional monitoring tool to release loads that do not contain implants. (See Class 5 definition) The use of Class 6 Emulating Indicators is presently not covered in any AAMI health-care facilities user documents.

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