Table 7—Types and applications for use of sterilization monitoring devices *(continued)*

	Test should be run three times consecutively in an empty chamber, except for table-top sterilizers, where the test should be run three times consecutively in a full load. Should be used for periodic product quality assurance testing.	Part of release criteria for changes made to routinely sterilized items, load configuration, and/or packaging.

NOTE 1—See Section 12 (New product evaluation) for general guidelines on how to assess the specific label claims of new products that become commercially available.

10.5 Sterilization process monitoring devices

10.5.1 Physical monitors

Physical monitors include time, temperature, and pressure recorders; displays; digital printouts; and gauges. For sterilizers with recording charts, the operator should check that the pen is functioning properly and ensure that when the chart is inserted, it is marked with the correct date and sterilizer number. For sterilizers with printouts, the printout should be checked to verify that the cycle identification number has been recorded and that the printer is functioning properly. At the end of the cycle and before items are removed from the sterilizer, the operator should examine and interpret the chart or printout to verify that all cycle parameters were met and initial it to permit later identification of the operator (see 10.3.1 and 10.3.2). Sterilizers that do not have recording devices should not be used.

NOTE 1—It is important that the chart or printout is readable.

NOTE 2—Most temperature sensors indicate temperature at the drain or exhaust line of the sterilizer, not at the center of packs. Improper load configuration or package composition can interfere with air evacuation and steam penetration, conditions that will not be revealed in the temperature recording. Therefore, physical monitoring and other indicators of sterilizer performance should never be considered a substitute for careful adherence to prescribed packaging and loading procedures.

If the interpretation of the physical monitors suggests inadequate steam processing, the contents of the load should not be dispensed or used. The interpreter should inform the appropriate supervisor, who should initiate appropriate follow-up measures.

Rationale: Physical monitoring provides real-time assessment of the sterilization cycle conditions and provides permanent records by means of chart recordings or digital printouts. Physical monitoring is needed to detect malfunctions as soon as possible, so that appropriate corrective actions can be taken.

10.5.2 Chemical indicators (CIs)

10.5.2.1 General considerations

Chemical indicators are designed to respond with a chemical or physical change to one or more of the physical conditions within the sterilizing chamber. Chemical indicators assist in the detection of potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer. 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. All CIs should be used in accordance with the CI manufacturer's written instructions.

ANSI/AAMI/ISO 11140-1:2005, *Sterilization of health care products—Chemical indicators—Part 1: General requirements*, defines six classes of CIs and specifies performance requirements for them:

Process indicators (Class 1) are intended for use with individual units (e.g., packs, containers) to indicate that the unit has been exposed to the sterilization process and to distinguish between processed and unprocessed units. These indicators are also referred to as external CIs.

Indicators for use in specific tests (Class 2) are intended for use in specific test procedures (e.g., the Bowie-Dick test) as defined in relevant sterilizer/sterilization standards. See 10.7.6 for recommendations concerning the use of these indicators. See also ANSI/AAMI/ISO 11140-5, *Sterilization of health care products—Chemical indicators—Part 5: Class 2 indicators for Bowie and Dick air removal test sheets and packs.*

Single-variable indicators (Class 3) are designed to react to one of the critical variables and intended to indicate exposure to a sterilization process at a stated value of the chosen variable.

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