

February 2007

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Learning Objectives

1. Discuss why you do both routine steam sterilizer efficacy monitoring and qualification testing.
2. Describe how to perform routine steam sterilizer efficacy monitoring in sterilizers larger than 2 cubic feet, table-top sterilizers, and flash sterilization cycles.
3. Describe how to perform steam sterilizer qualification testing in sterilizers larger than 2 cubic feet, table-top sterilizers, and flash sterilization cycles.

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Routine steam sterilizer efficacy monitoring and steam sterilizer qualification testing - Why & how

by Martha Young, BS, MS, CSPDT

Are you confused about the difference between routine steam sterilizer efficacy testing and qualification testing? The Association for the Advancement of Medical Instrumentation's (AAMI's) newest hospital recommended practice, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* (ANSI/AAMI ST79:2006) require both types of testing in Section 10 Quality control.

Section 10.7 discusses routine sterilizer efficacy monitoring:

Routine sterilizer efficacy monitoring is establishing a regular pattern of testing the efficacy of the sterilizer with Bowie-Dick tests (BD), physical monitors, external and internal chemical indicators (CIs), and biological indicator process challenge devices (BI PCDs).

Section 10.8 discusses sterilizer qualification testing:

Sterilizer qualification testing is testing the sterilizer with physical monitors, external and internal chemical indicators, Bowie-Dick tests and biological indicator process challenge device "after sterilizer installation, relocation, malfunction, major repairs, and sterilization process failures."¹

Routine sterilizer efficacy monitoring and qualification testing are divided into sections based on the type of sterilization process used:

- sterilizers larger than 2 cubic feet;
- table-top sterilizers;
- and flash sterilization cycles.

Table 7 in AAMI ST79 provides an overview of sterilization process monitoring.¹

This inservice will discuss the why and how to perform routine steam sterilizer efficacy monitoring and steam sterilizer qualification testing.

Routine steam sterilizer efficacy monitoring

Routine sterilizer efficacy monitoring should be done to ensure the steam sterilizer is effectively sterilizing medical devices. Why and how to use each monitoring

tool for routine steam sterilizer efficacy monitoring as recommended by AAMI ST79 is discussed.¹

Bowie-Dick testing daily in each dynamic-air-removal sterilizer (e.g., prevacuum):

The Bowie-Dick (BD) test is a "sensitive and rapid means of detecting air leaks, inadequate air removal, and inadequate steam penetration and the presence of noncondensable gases."¹ All of these situations can "defeat sterilization and result in nonsterile supplies if undetected."¹

A healthcare facility prepared BD PCD or a commercially available BD PCD that has been cleared by FDA as equivalent to this type of BD PCD can be used.¹ A Class 2 chemical indicators is used inside the PCD. The test pack is placed on the bottom shelf, over the drain in an empty sterilizer.

A sterilizer malfunction is indicated if:

"Any unexpected color change, such as the center of the test sheet being paler or a different color than the edges (i.e., there is a nonuniform color change), indicates there was an air pocket present during the cycle due to sterilizer malfunction."¹

Rerun the test and if the test again shows a nonuniform color change, shut down the sterilizer and call for service. If the second test shows a pass, continue to use the sterilizer.

Physical monitoring of each load

This is the first monitoring tool for the load that can detect a sterilization process failure as a result of incorrect cycle parameters for the load contents. Check at the beginning of the cycle that the chart is marked with the correct date, sterilizer and cycle identification number. "At the end of the cycle and before the 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 to permit later identification of the operator."¹ If the physical monitoring results are not correct, do not release the load and start a sterilization process investigation.

External chemical indicators on the outside of each package

External chemical indicators (CIs) “differentiate between processed and unprocessed items” so that incorrectly processed items are not released for use.¹ A Class 1 process indicator is used on the outside of each package unless the internal chemical indicator is visible. If the external CI has not reached its acceptable endpoint, do not release the load and start a sterilization process investigation. This CI should also be examined “before use of the item to verify that the item has been exposed to the sterilization process.”¹

Internal chemical indicators inside each package, tray or rigid sterilization container system

Internal CIs “may allow detection of equipment malfunctions (e.g., air leaks, wet steam, inadequate temperature or time)” or detect incorrect packaging, loading, and the incorrect cycle parameters for the load contents.¹ If not used, you will not know that the sterilant penetrated each package, tray or rigid sterilization container system. Place a Class 4 or Class 5 chemical indicator in the area considered to be the greatest challenge to sterilant penetration (e.g., corners of rigid sterilization container systems and next to the largest heat sink). Train the user who will retrieve the CI to interpret the results and to reject and return the unused package, tray or rigid sterilization container system to be reprocessed if the CI does not reach its acceptable endpoint. At that time the sterilization processing department head should decide whether to recall that sterilized load based on the physical monitors and the results of other CIs in the load and the BIs.¹ “If biological monitoring was performed but the results are not yet available, the remaining packages from the same load should be quarantined and not used until the BI results are obtained.”¹ As with any monitoring tool that detects a sterilization process failure, an investigation should be initiated.

Biological indicators weekly, preferably daily and in each load of implants which should be quarantined until the BI is negative

“Biological indicators are the only sterilization process monitoring device that provides a direct measure of the lethality of the process.”¹ Therefore, this is the only monitoring tool that tells you that spores were killed which is the goal of the sterilization process. Optimally, running a BI in each load would verify the sterilization efficacy of each cycle and if the loads are

Table 7—Sterilization process monitoring recommendations				
Routine load release (see 10.6)		Routine sterilizer efficacy monitoring (see 10.7)	Sterilizer qualification testing (after installation, relocation, malfunctions, major repairs, sterilization process failures) (see 10.8)	Periodic product quality assurance testing (see 10.9)
Nonimplants	Implants			
Physical monitoring of cycle	Physical monitoring of cycle	Physical monitoring of cycle	Physical monitoring of cycle	Physical monitoring of cycle
External and internal chemical monitoring of packages	External and internal chemical monitoring of packages	External and internal chemical monitoring of packages	External and internal chemical monitoring of packages	Placement of BIs and, CIs within product test samples
Optional monitoring of the load with a PCD containing one of the following: <ul style="list-style-type: none"> • a BI • a BI and a Class 5 integrating indicator • a BI and an enzyme-only indicator • a Class 5 integrating indicator • an enzyme-only indicator 	Monitoring of every load with a PCD containing a BI and a Class 5 integrating indicator or a PCD containing a BI and an enzyme-only indicator	Weekly, preferably daily (each day the sterilizer is used), monitoring of a full load with a PCD containing a BI. (The PCD may also contain a CI.) In flash sterilizers, monitoring is done in an empty chamber. For dynamic-air-removal sterilizers, daily Bowie-Dick testing in an empty chamber	Monitoring of three consecutive cycles in an empty chamber with a PCD containing a BI. (The PCD may also contain a CI.) For dynamic-air-removal sterilizers, monitoring of three consecutive cycles in a empty chamber with a Bowie-Dick test pack	
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quarantined until the BI is negative, patient contact with non sterile medical devices and recalls could be eliminated.

A BI should be placed inside a process challenge device (PCD) that is representative of the load being monitored and that is “equal to or greater than the challenge posed by the most difficult item routinely processed.”¹

If a sterilizer is designed to be used for multiple types of cycles then each sterilization cycle should be tested because they create different types of challenges for air removal and steam penetration:

- gravity-displacement at 132°C to 135°C [270°F to 275°F]
- gravity-displacement at 121°C [250°F]
- dynamic-air removal at 132°C to 135°C [270°F to 275°F]
- flash at 132°C to 135°C [270°F to 275°F]
- flash with single wrapper or other packaging¹

In addition, for flash sterilization each type of tray configuration routinely processed should be tested because they each create a different challenge to air removal and steam penetration during the sterilization process:

- perforated, mesh-bottom, open surgical tray
- rigid sterilization container system
- protective organizing case
- single-wrapped surgical tray¹

Testing each load with a BI PCD ensures that each sterilization cycle for which the sterilizer is designed and each type of flash tray configuration

used is routinely tested as recommended by AAMI ST79.

If a BI is positive the load should not be used. If the load has been released then all packages processed since the last negative BI need to be recalled and reprocessed.¹ Running a BI PCD in each load and quarantining until the BI is negative will eliminate the need to recall.

Sterilizers larger than 2 cubic feet

The BI PCD used to test this size sterilizer is the AAMI routine 16-towel pack or a commercially available BI PCD that is cleared by FDA for this intended use.¹ The BI PCD should be placed on the bottom rack, over the drain in a full load in each type of cycle for which a sterilizer is designed.¹

Table-top sterilizers

The BI PCD for table-top sterilizers should represent the same type of package or tray routinely processed through the sterilizer and should be run in each type of cycle for which the sterilizer is designed.¹ Select the most difficult package or tray to sterilize from those most frequently processed.

The BI PCD should contain one or more BIs and one or more CIs and be run in a full load because that is the greatest challenge to air removal and steam penetration in a table-top sterilizer due to the limited amount of steam per load.¹ Check with the sterilizer manufacturer about the most challenging area to place the BI PCD in the chamber.

See **SELF-STUDY** on page 38

SELF-STUDY from page 37

Flash sterilization cycles

The BI PCD should be representative of the same type of tray that is routinely processed:

- perforated, mesh-bottom, open surgical tray;
- rigid sterilization container system;
- protective organizing case;
- single-wrapped surgical tray.¹

In addition, each type of cycle for which a sterilizer is designed should also be tested.

The BI PCD is placed on the bottom rack, over the drain in an empty load. Empty chamber testing creates the greatest challenge because it minimizes the effect of heat-up time on spore kill that occurs when a heavy metal mass is in the load.

Implants

A BI PCD containing a BI and a Class 5 integrating indicator should be run in each load that contains an implantable. The load should be quarantined until the BI is negative.¹ The implant should not be used if the BI is positive. There are no short cuts when processing implants.

Record keeping should document the results of each load

Record keeping "ensures that the sterilization process is monitored as it is occurring, ensures that cycle parameters have been met, and establishes accountability.¹ In addition, documentation helps personnel determine whether a recall is necessary."¹

Lot control numbers should be assigned to each package used or each flash sterilization load to facilitate a recall.¹ For each sterilization cycle the following information should be recorded.

- lot number;
- contents of load;
- exposure time and temperature if not on a recording chart;
- operator identification;
- results of BI testing;
- results of the Bowie-Dick testing;
- results of chemical indicator in the PCD (BI challenge test pack, BI challenge test tray, CI challenge test pack);
- any reports of inconclusive or non responsive CIs in the load.¹

Sterilizer maintenance records should be included in order to determine when steam sterilizer qualification testing needs to be performed.

Steam sterilizer qualification testing

Qualification testing is done to assess whether the sterilizer is functioning properly after an event has occurred which may affect sterilizer performance.

These events and reasons for testing include:

- sterilizer installation or relocation to assess sterilizer performance in the environment in which it will be used;
- sterilizer malfunctions or process failure to ensure the sterilizer is performing to specifications after a malfunction or process failure;
- sterilizer major repairs to ensure the sterilizer is performing to specification after a major repair;
- a major repair is a repair outside the scope of normal maintenance. This includes weld repairs of the pressure vessel, replacement of the chamber door or major piping assembly, or rebuilds or upgrades of controls. Normal preventive maintenance, such as the rebuilding of solenoid valves or the replacement of gaskets, is not considered major repair. Changes to the utilities connected to the sterilizer such as those that result from a water-main break, annual boiler maintenance, additional equipment loads and installation of new boilers should be treated as major repairs.¹

Physical monitors, as well as internal and external CIs should be used the same way as described in the above section on routine steam sterilizer monitoring. BI and BD PCDs are also used but are each run in three consecutive cycles to obtain information about the consistent performance of the sterilizer after an event occurs. For this testing, a cool loading cart should be used for each cycle "to prevent superheating in the chamber (which can affect the test results) and more closely duplicates normal processing procedures."¹ Record keeping should identify the types of BI PCDs used, the cycles tested, the BI results, the results of CIs in the BI PCDs, and the BD PCD results.

Sterilizers larger than 2 cubic feet

The AAMI 16-towel BI PCD or a commercially available BI PCD of equivalent performance can be used. Three consecutive empty cycles

should be run, one right after the other. This testing is followed by three consecutive empty cycle test-

ing with a BD PCD in dynamic-air-removal (e.g., prevacuum) sterilizers.¹ "In qualification testing, it is preferable to run the Bowie-Dick test cycles after the BI PCD test cycles because it is important to establish first that the sterilizer is capable of achieving biological kill so that the subsequent Bowie-Dick test cycles will be run under "best-case" conditions."¹ For both types of testing, the PCD should be placed on the bottom rack, over the drain.

As with routine sterilizer monitoring this BI PCD testing should be done in each type of cycle for which the sterilizer is designed:

- gravity-displacement at 132°C to 135°C [270°F to 275°F]
- gravity-displacement at 121°C [250°F]
- dynamic-air removal at 132°C to 135°C [270°F to 275°F]
- flash at 132°C to 135°C [270°F to 275°F]
- flash with single wrapper or other packaging

Table-top sterilizers

A representative package or tray that is routinely processed and considered difficult to sterilize should be used as the BI PCD. The BI PCD should contain one or more BIs and one or more CIs. As with routine sterilizer monitoring, each type of cycle for which the sterilizer is designed should be tested. In table-top sterilizers the BI PCD is run in three consecutive cycles in a fully loaded chamber and the load quarantined until the BI results are available.

Flash sterilization cycles

One or more BIs and one or more CIs should be placed in the most challenging area of the BI PCD. The BI PCD should be representative of the same type of tray that is routinely processed. Select only one of the following as the BI PCD:

- perforated, mesh-bottom, open surgical tray
- rigid sterilization container system
- protective organizing case
- single-wrapped surgical tray

As with routine sterilizer monitoring, each type of cycle for which the sterilizer is designed should be tested. The BI PCD is run in three consecutive empty cycles. If a dynamic-air-removal sterilizer (e.g., prevacuum) is used for flashing, this testing is followed by three consecutive empty cycle testing with a BD PCD.

Summary

The Association for the Advancement of Medical Instrumentation's (AAMI's) newest hospital recommended practice, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* (ANSI/

Types of Testing	Sterilizers larger than 2 cubic feet	Table-Top Sterilizers	Flash Sterilizers
Routine Efficacy Monitoring	Full Load	Full Load	Empty Load
Qualification Testing	Empty Load 3 Consecutive Cycles	Full Load 3 Consecutive Cycles	Empty Load 3 Consecutive Cycles

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AAMI ST79:2006) recommends both types of testing in Section 10 Quality control.

Routine steam sterilizer efficacy monitoring establishes a regular pattern of testing the efficacy of the sterilizer with Bowie-Dick tests, physical monitors, external and internal chemical indicators, and biological indicator process challenge devices.

Sterilizer qualification testing is testing the sterilizer with physical monitors, external and internal chemical indicators, Bowie-Dick tests and a biological indicators process challenge device "after sterilizer installation, relocation, malfunction, major repairs, and sterilization process failures." This testing is only done after one of the defined events occur.

The type of BI PCDs used are the same for both types of testing for each of the sterilization processes tested (sterilizers larger than 2 cubic feet, table-top sterilizers, and flash sterilization cycles). The type of load used and number of cycles run varies as shown in the table on the preceding page.

In routine steam sterilizer efficacy monitoring and steam sterilizer qualification testing each type of cycle for which the sterilizer is designed must be tested because they all create a different challenge to air removal and sterilant penetration. For routine steam sterilizer efficacy monitoring in flash sterilizers, the BI is placed in the same type of trays that are routinely processed to create all the packaging challenges routinely used. In steam sterilizer qualification testing in flash sterilizers only one BI PCD needs to be used but each type of cycle for which the sterilizer is designed must be tested. **Testing each load with a BI PCD ensures that each sterilization cycle for which the sterilizer is designed and each type of flash tray configuration used is routinely tested as recommended by AAMI ST79.**

The AAMI ST79 recommended practices requires both types of testing to ensure that the sterilization process is functioning on a routine bases and after an event that could effect the efficacy of the sterilizer. **HPN**

Martha Young, BS, MS, CSPDT is a senior international technical service specialist in 3M Medical Products, St. Paul, Minnesota. She has over twenty five years of experience in the area of sterilization and disinfection.

References

1. Association for the Advancement of Medical Instrumentation. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST79, 2006.

2. Young, Martha No Short Cuts! Monitoring Implant Loads. HPN. Dec 2006.

Routine steam sterilizer efficacy monitoring and steam sterilizer qualification testing - Why and how!

Circle the one correct answer

1. Routine steam sterilizer efficacy monitoring establishes a regular pattern of testing the efficacy of the sterilizer with Bowie-Dick tests, physical monitors, external and internal chemical indicators, and biological indicator process challenge devices (BI PCD).
A. True
B. False
2. Sterilizer qualification testing is testing the sterilizer with physical monitors, external and internal chemical indicators, Bowie-Dick tests and a biological indicator process challenge device after sterilizer installation, relocation, malfunction, major repairs, and sterilization process failures.
A. True
B. False
3. Each type of sterilization cycle for which the sterilizer is designed should be tested with a BI PCD when performing routine steam sterilizer efficacy monitoring and steam sterilizer qualification testing.
A. True
B. False
4. The BI PCD used to test table-top sterilizers for routine steam sterilizer efficacy monitoring and steam sterilizer qualification testing should be representative of the same type of package or tray routinely processed and run in each type of cycle for which the sterilizer is designed.
A. True
B. False
5. Each type of tray configuration should be tested with a BI PCD when performing routine steam sterilizer efficacy monitoring in a flash sterilization cycle but only one type of tray configuration should be tested when performing steam sterilizer qualification testing.
A. True
B. False
6. A major repair of the sterilizer includes weld repairs of the pressure vessel, replacement of the chamber door or major piping assembly, or rebuilds or upgrades of controls.
A. True
B. False
7. A major repair of the utilities connected to the sterilizer includes a water-main break, annual boiler maintenance, additional equipment loads and installation of new boilers.
A. True
B. False
8. The BI PCD is placed in a full load when performing routine steam sterilizer efficacy monitoring in sterilizers larger than 2 cubic feet and table-top sterilizers.
A. True
B. False
9. The BI PCD is placed in an empty load when performing routine steam sterilizer efficacy monitoring in flash sterilization cycles.
A. True
B. False
10. The BI PCD is placed in three consecutive empty loads when performing steam sterilizer qualification testing in sterilizers larger than 2 cubic feet and flash sterilization cycles and in three consecutive full loads when performing steam sterilizer qualification testing in table-top sterilizers.
A. True
B. False

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