# STERILIZATION MONITORING: AN UPDATE


**INFECTION PREVENTION CORNER**
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*Author's note: This subject is by far one of the most important aspects of infection prevention that I can stress to you, providing safety for your patients and staff and reducing a legal and financial risk management issue for you.*

*This latest update is was prompted by a couple of things. The nomenclature for the sterilization monitors has changed recently and having updated this information in AzDF's current IP/OSHA Flash drive along with new tools to work with, I wanted to get the changes in the Inscriptions. In addition, I have had some recent feedback from a dental industry leader, whose company markets sterilizers, who contends that the standards of dental sterilization do not need to be the same as in the medical field. I strongly disagree. The standards for both should be the same. Let's do it!*

## Learning Objectives:

After reading this article, the reader should be able to:

- narrow the gap between monitoring sterilizers and obtaining results;
- reduce the risk of releasing non-sterile instruments for patient care;
- manage documentation of sterilization results for risk management purposes;
- identify the steps to take for managing positive monitor results.

## Then and Now: Varied Infection Control Standards

When we first moved to Phoenix and my husband started his dental practice, as an infection control nurse, I was curious as to how dentistry dealt with infection control. What I soon found out was that dental offices did not have the same standards as the hospitals regarding disinfection and sterilization. Instruments were sterilized in perforated-steel cylinders and then placed in drawers with no thought to keeping them sterile for patient care. I was aghast. Over the years, the gap had narrowed quite a bit due to educational opportunities from infection control experts in the dental field and our ability to access information more readily. But the deciding factor has been government intervention and establishment of standards and guidelines. The fact remains that sterilization practices should be the same in both venues. But now the gap is widening again. Why? Because our CDC Dental Guidelines had not been updated since 2003[1] and since then there have been changes in sterilization standards. Fortunately, there is updated guidance in the CDC Recommended Infection-Control Practices for Dentistry published in 2016[2] which has been a help, but many dentists do not want to update their monitoring unless it is mandated. With that mindset they are compromising the risk-management component of their practices.


*Figure 1: 2016 CDC Updates on 2003 Dental Guidelines*

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## CDC and BODEX History

In 1986, the Centers for Disease Control and Prevention (CDC) first published Recommended Infection-Control Practices for Dentistry.[3] These dental guidelines recommended weekly biological monitoring of sterilizers. Other than dental facilities that were government run, this was virtually unknown to dentists. Even if they did know about it, it was not an easy task to do. By 1993, new CDC dental guidelines were published[4] and continued to stress the weekly biological monitoring and in addition, recommended that an external monitor should be placed on the outside of each package. It still was a non-issue in Arizona as there was no enforcement mechanism. That changed in 1994 when the Arizona State Board of Dental Examiners (BODEX) initiated their Infectious Disease Control Inspections. As part of the standard of care required by BODEX, dentists were expected to follow the most current CDC guidelines and Occupational Safety & Health Administration (OSHA) regulations. Because of these guidelines and laws, some dental schools started offering a mail-in program to their alumni so they could meet the standard of care. That was about all one could do unless they bought an in-house monitoring program with the incubator and biological indicators and recorded their findings. This seemed like a lot of work and word was passed around that the records kept in-office would not be acceptable to government officials if inspected. That was not true, but it was widely accepted. It seemed much easier to mail in your monitors.

## The Present

In my experience, the most widely used method to biologically monitor steam sterilizers in dental offices still is the mail-in system. Envelopes come with monitoring strips, and the strips are run in the autoclave during sterilization cycles. The strips are then mailed to a dental school or a monitoring company for incubation and reading. A positive reading is called back to the office for prompt attention. Quarterly reports and yearly reports are provided for documentation for various government entities. A few offices only test monthly, if that, but most dental offices and clinics I have seen are testing weekly according to the CDC recommendations. That is great news. We have finally caught up to what we should be doing, right? Well, actually, no, not really. Think about it. The tests are read in 24 hours but factoring in the time it takes for the mail to arrive at the testing facility, it could take a week or more. One dentist in Tucson told me the tests were mailed to Canada, not a good turnaround.

## Monitoring Steam Sterilization

The steam sterilizer, or autoclave, that provides moist heat and saturated steam under pressure, is the oldest acceptable method for sterilizing instruments.[5] Steam sterilizers are the method of choice used to render instruments sterile in the dental setting.[6] The steam sterilizer, also known as an autoclave, is a device that is used to sterilize surgical instruments and other critical items that are reused for patient care. The gold standard for steam sterilization is achieving a temperature of 250 degrees and 15 PSI (pounds per square inch of pressure) for 30 minutes—*not including the warm-up or drying cycles*. These *three critical parameters* have been tweaked over the years by autoclave manufacturers by decreasing the chamber volume, increasing temperatures and other methods to achieve more rapid sterilization cycles. How these parameters are measured to insure sterilization has also evolved. The steam cycle is monitored by mechanical, chemical, and biological monitors.

## Who's Amy?

There is an organization known as the Association for the Advancement of Medical Instrumentation (AAMI, pronounced Amy). AAMI has a membership comprised of various professionals, engineers, nurses, physicians, and others who bear the responsibility for setting the standards for patient safety in the handling of patient care items, instruments, and other items that pass through the hospital sterile processing centers. This organization sets the standards for the healthcare industry in sterilization and sterilization monitoring. It has provided standards that are closely followed by hospital sterile processing centers. Their comprehensive guide to steam sterilization and sterility assurance in health care facilities is very precise and can be intimidating to the uninitiated. I will highlight the areas that we can use for dental practice. The nomenclature of these monitors has been changed from "Class" to "Type."

**Types of Chemical Monitors for Use in Dentistry**

*Type 1 (process indicators)* show the package has been processed in the sterilizer. They should be placed on the outside of each package.

*Type 2 (Bowie-Dick type indicators)* are used for dynamic-air-removal sterilizers to monitor vacuum functioning. Run daily before use. Check manufacturer's instructions to see if needed.

*Type 4 (multi-variable indicators)* measure two or more critical parameters of the sterilization cycle. Read at chairside for final release for clinical use.

*Type 5 (integrating indicators)* measure all the critical parameters of the sterilization cycle and are comparable to biological indicators. Use for load release.

## Use of Chemical Monitors in Dentistry

In hospitals, steam sterilizers are monitored by reading a printout that has recorded the sterilization time period at the appropriate temperature, and pressure, and are part of their load release criteria. Many of the sterilizers used in dentistry do not provide printed data for sterility



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assurance. So we have to rely more heavily on the use of chemical monitors for load and use release. In the past few years, manufacturers have made available to the dental community sterilization pouches with ink change markers both inside and outside of the packs, in compliance with 2003 CDC guidelines[7]. If you read the latest 2016 CDC guidance documents[8], there are now more advanced chemical monitors that hospitals have been using in sterilizer loads and in individual packaging and now available to dentistry.

*Figure 2: Type 1 chemical indicator*

We are already using the *type 1* indicator in the form of tape on wrapped cassettes or on the outside of the sterilization pouches to show that the packs have been processed. If you have a dynamic-air-removal sterilizer, you may need to monitor with the *type 2* indicator daily at the beginning of the day. Check with the manufacturer of your sterilizer to see if you need to do this. A *type 4* indicator should be placed inside each cassette or sterilization pouch so that when the pack is opened for use at chairside, it validates that the instruments are safe to use.

*Figure 3: Bowie-Dick type test pack with processed and unprocessed tests*

The good news is now you may purchase, for just a couple dollars more per 200 packs, sterilization pouches that have the type 4s already inside. The expense is less than purchasing individual strips and is a time saver for staff. *They are now also being called multi-parameter or multi-variable*. If you do not look for this labeling, you are only purchasing pouches that have type 1 or 2 indicators inside.

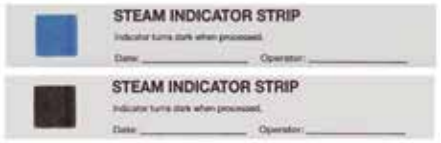


*Figure 4: Type 4 indicator strips, Top: unprocessed, bottom: processed*


*Figure 5: sterilization pouch with type 4 already inside*

*Type 5 integrators* are extremely reliable. They are widely used in hospitals to monitor all the critical parameters required. They can be used in both passive and active vacuum steam sterilizers. They are easy to read and have a very distinct pass/fail criteria. Use one Type 5 in a challenge pack for each load. A challenge pack is placing an integrator in the same type of packaging as what is being run in the sterilizer load, i.e., either sterilization pouch or cassette. Place it in the middle of the sterilizer. At the end of the cycle, open the package with the Type 5 indicator. Use the reading of the integrator as criteria for load release.


*Figure 6: Passed type 5 integrators in challenge packs*

Do not release the load if the integrator fails. Record all results in a record-keeping notebook. I like to call the Type 5 "the silver bullet" as its use in every sterilization cycle prevents the release of unsterilized instruments for patient use.

## Biological Monitoring in house

In addition to chemical monitoring, each sterilizer should be biologically monitored at least week.

*Figure 7: solid state waterless incubator*


*Figure 8: left BI fail; right pass*

The effectiveness of steam sterilization is monitored with a biological indicator (BI) containing spores of *Geobacillus stearothermophilus* (formerly *Bacillus stearothermophilus*). You can easily set up your in-house system. I did it in the 80's; it is not rocket science. It is a much less expensive procedure than using the mail-in systems once you buy the incubator and you get the BI monitors results in 24 hours. If you have one sterilizer, you will need two biological monitors to test, one to run in the sterilizer and one as a control that you do not run in the sterilizer. Place both in the incubator. The BI that is run in the sterilizer should not respond to incubation, but the control will. If you have two sterilizers, you will only need 3 biological monitors if you run the tests for the sterilizers at the same time as you only need one control. The more sterilizers you have, the more money you will save in biological monitoring expense and that will in turn pay for the type 4s and type 5s. It should be a wash. To run a test, place a BI into a challenge pack and run with a full load of wrapped items. Biological monitoring is part of the load release criteria and used for recall of loads. Keep records of all biological monitoring for three years. If you are not sterilizing implants, which need each load biologically monitored, it is sufficient to run



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BIs once a week. *However, placing a type 5 integrator in each load will safely cover the loads run between biological monitoring.*

## Common Factors in the Improper Use of Sterilizers

- Chamber overload
- Low temperature setting
- Inadequate exposure time
- Failure to preheat the sterilizer
- Interruption of the cycle

## In Case of Sterilizer Failure

In the past if a sterilizer had a positive reading from a BI, we could still use the sterilizer. We did have to retest and if the second BI test also failed, the sterilizer had to be pulled from use, repaired and retested with negative results before it could be used. That is no longer the case. Since 2006, AAMI has set the standard that if the sterilizer has a positive reading, it should be pulled from use immediately. Because this is now the standard, it is very wise to have at least two sterilizers. If one is down, you still have another to use. I also recommend having at least two sterilizers as it increases the efficiency of processing instruments. After evaluation of the sterilizer and review of the procedures used for processing, the sterilizer should be tested again with BIs three consecutive times with negative results before it can be put back to use. If one or more of the BI's are positive, then the sterilizer needs further evaluation, repair and testing. If you are using the mail-in monitors, by the time we find out about a failure, it may be several days and all the instruments in question may already have been used again on unsuspecting patients. When the mail-in BIs are used, with three rounds of additional testing, it would be weeks before you could put the sterilizer back in use.

**Steam Sterilization Protocol in Management of Biological Indicators**

- Take sterilizer out of service
- Pull all objects processed since last negative BI
- Reprocess implantable objects
- Review sterilization and monitoring procedures for correctness
- Repeat BIs in 3 consecutive sterilization cycles
- If all 3 BIs are negative, return to service
- If one or more BIs are positive, sterilizer must be submitted for further evaluation and repair if necessary

## Documentation

When you read the 2016 CDC Guidance documents you will see that it stresses maintaining sterilization records, not only the weekly BI tests but each load. Are you doing this? Step-by-step procedures for sterilizer monitoring and maintenance including documentation forms can be found in the Infection Prevention Folder included in the 2019 IP/OSHA Toolkit Flash Drive available on the AzDA website, azda.org using search word "Toolkit." CDC Guidance documents are included.

*Figure 9: Sterilizer record*

## Whose job is it?

It is the responsibility of the entire clinical staff to understand the monitor readings so packages can be pulled before use if the readings indicate an incomplete sterilization cycle.

## Costs if You DO NOT Introduce New Sterilization Monitoring Methods to Your Facility (INFECTION CONTROL AND EPIDEMIOLOGY OF DISEASE)

If the sterilizer fails and instruments that were processed in it were used on patents, it would be considered a bloodborne exposure incident. All patients involved, both source patients and exposed patients would have to be baseline tested for hepatitis B, hepatitis C and HIV. If not all of the source patients are willing to be tested, or if one of the source patients tests positive for any of the bloodborne diseases, all exposed patients will have to be tested at six weeks, three months and six months for signs of the bloodborne diseases.

If the exposed patients are not immune to hepatitis B, they should be provided a vaccination series and then retested. If caught soon enough, the non-immune patients should be given Hepatitis B Immune Globulin in addition to the vaccination series. If any patient becomes infected with a bloodborne disease as a result of the incident, then it must be reported to the health department.

Will it cost a lot more for an exposure investigation than updating your monitoring methods? Yes. A safe estimate is tens of thousands of dollars even if caught within 48 hours, considerably more if discovered after a two-week period which represents a non-functioning sterilizer for a week and then waiting a week for results.

But WAIT, you say: "I rarely, if ever, have sterilizer failures. I do no have to worry about any of this. I do not have to do this." No, you don't have to do anything. But, what about operator error? According to one study, operator error, rather than mechanical malfunction caused 87% of sterilization failures. It is a common reason for sterilizer failure. Do you have temporary personnel working for you or someone new who is not sure about how to run the sterilizer and is afraid to ask? Think about that. Also know that as the updated monitor-



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ing systems are now becoming the standard of care, you have a legal and ethical responsibility to follow them to ensure that your instruments are sterilized between patient use. An experienced dental assistant should be responsible for the sterilizer monitoring and recording. In teaching the process to someone new to the procedure, demonstration and return demonstration should be employed. Do not assume that the employee understands the process completely. Constant supervision must be employed to ensure that the procedures are done correctly.

## In Summary

The hospitals are using new technologies that narrow the gap between testing and reading the monitors. If we use our present mail-in system, it can be days before we hear anything and it can put our patients at risk. But there are other ways to monitor our sterilizers more efficiently. In the first line of monitoring, we should use type 1 chemical indicators on the outside of our packages (autoclave tape or ink change on sterilization pouches to show that the packs have been processed in the sterilizer. Using the type 5 integrators in each load, gives us results for load release and the type 4s in each package is the final monitor to read before instrument use, protecting your patients, staff and practice. Consider in-house biological monitoring.

## Purpose

Work to narrow the gap between the monitoring and the results, reducing the risk of releasing non-sterile instruments for patient care. ■

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