Back to Basics: Sterilization Monitoring in the Dental Office
November 16, 2015

During the busy clinic day, one may not give much thought to the mundane task of sterilization monitoring, but a breach in this important infection control measure can compromise the health of both staff and patients. Sterilization monitoring helps identify a malfunctioning sterilizer or improper processing procedures. This article provides the dentist and staff with information to successfully monitor sterilization using physical, chemical and biological indicators, all of which are necessary to assure effective sterilization. A summary of services offered by four independent and nine university-based sterilization services is also provided.

Three types of sterilization are available to dentists—steam, dry heat and unsaturated chemical vapor. Steam sterilization depends upon steam contacting a microbe and transferring sufficient heat to denature proteins, killing the microbe within a short time period.

This article focuses on monitoring steam sterilization. Effective steam sterilization depends on four tenets: 1) lowering and limiting bioburden before sterilization, 2) properly preparing items for sterilization, 3) selecting the appropriate sterilization parameters, and 4) maintaining sterility until sterilized items are used.

The phases of the steam sterilization cycle are:

- Preconditioning phase: Phase of a steam sterilization cycle during which air is removed from and steam is injected into the sterilizer chamber.¹
- Holding phase (also called exposure phase or holding time): Phase immediately following the preconditioning phase in which the load must be held at the specified temperature and period of time to achieve sterilization.¹
- Exhaust phase: Phase in which the steam is exhausted from the chamber.
- Drying phase: Phase in which steam-sterilized items are dried for a required period of time within the sterilizer before they are handled.¹

Factors that result in inadequate sterilization include not cleaning dental instruments thoroughly, thus preventing steam from reaching the instrument surfaces, and
placing too many instruments in a pouch or overloading the sterilizer. There must be
adequate space around items within and around pouches to allow steam to circulate.
Time, temperature and saturated steam are critical variables required to achieve
sterility.\textsuperscript{2} Mechanical, physical, and biological indicators are used to monitor these
critical variables.

**Physical (Mechanical) Indicators**

Physical (or mechanical) monitoring of a sterilization load is the most basic means
of monitoring for sterilization efficacy. Examples of physical indicators include
equipment gauges and graphs or printouts showing exposure time and
temperature. An inadequate time or temperature reveals a problem with the
sterilizer, but will not detect improper packaging of items or sterilizer loading.

**Chemical Indicators**

The U.S. Centers for Disease Control and Prevention (CDC) recommends using
internal chemical indicators inside each load to ensure that conditions inside the
pouch will sterilize the contents.\textsuperscript{2} Chemical indicators are impregnated with a
chemical that undergoes a reaction and produces a color change when reaching
the critical variable(s). Manufacturers must specify the stated value for the critical
variables that their indicator is designed to reach. The indicator’s packaging or
instructions provides the performance criteria for the critical variables, such as
121° C at 15 minutes.

The most basic type of chemical indicator is a **Type 1** “exposure” or process
indicator, such as tape or strips on the outside of pouches, where arrows change
color or stripes appear.\textsuperscript{3} This type of indicator only shows that the items have
been exposed to heat and steam. It is simply meant to distinguish a pack that has
been placed in the sterilizer from a non-sterile pack yet to be processed. Even an
insufficiently short exposure time will cause this color change.

**Type 2** chemical indicators have a specific function, which is to assess
homogenous distribution of steam into the center of a test pack during the
preconditioning phase of a steam sterilization cycle. The Bowie-Dick test
assesses this function and can be an early indicator of sterilizer malfunction.\textsuperscript{3} If
cool air is incompletely removed from the autoclave chamber, heat transfer from
steam will not penetrate the test pack to the Bowie-Dick indicator in the prescribed
time.

According to the Association for the Advancement of Medical Instrumentation’s
“Comprehensive guide to steam sterilization and sterility assurance in health care
facilities” (ANSI/AAMI ST79:2010), the recommendation advises the end user to
perform a Bowie-Dick test each morning, by itself, before the first load, and after
installation or repair.\textsuperscript{4} Per the 2003 CDC Infection Control Guidelines, the interval
for Bowie-Dick testing is given in the sterilizer manufacturer’s instructions.\textsuperscript{2}
This test is intended for sterilizers that employ dynamic air removal (pre-vacuum, high-vacuum, or steam-flush-pressure-pulse). Gravity displacement, the other type of air removal, is not considered dynamic air removal. The ADA Professional Product Review, Volume 2, Issue 2, provides a lab evaluation of steam sterilizers representative of the different types of air removal. The sterilizer operating manual should indicate the type of air removal it uses.

Sterilizer vacuum performance is acceptable if the sheet inside the test pack shows a uniform color change. On the other hand, entrapped air will cause a spot to appear on the center of the test card due to the inability of the steam to reach the chemical indicator at that location. Air leaks, inadequate air removal, inadequate steam penetration, and presence of non-condensable gases from boiler additives are all causes of test failure, and create a different appearance on the test card. Therefore, saving the failing card or photographing it will help the manufacturer troubleshoot the problem.

If the pre-vacuum sterilizer fails the Bowie-Dick test, do not use the sterilizer until it is inspected by the sterilizer maintenance personnel and passes the Bowie-Dick test. There are FDA-cleared, disposable or reusable test packs available for the Bowie Dick test if you do not want to construct your own. Figures 1 and 2 are examples of reusable test packs.

Figure 1. Reusable Bowie Dick Test Pack by SPS Medical, Inc.

Figure 2. Reusable Bowie Dick Test Pack by SteriPak.

Type 3, 4, 5 and 6 indicators are “internal” indicators. They are placed inside individual load items to assess attainment of the critical process variable(s) at the point of placement.
**Type 3** indicators are single parameter indicators placed inside the pouch or pack. They only monitor one critical variable, either temperature or time. Because of that, another parameter may not be reached and may go undetected.

**Type 4** indicators are multi-parameter internal indicators, and therefore provide greater assurance that sterilization conditions have been met because they measure two or more parameters. The package inserts of chemical indicators state values that the indicator reaches during the sterilization cycle for the critical variables. The stated values must match the cycle program you are monitoring. Some chemical indicators and integrators are specific for gravity displacement or dynamic air removal.

**Type 5** indicators measure all three parameters—time, temperature and presence of steam—but they are designed to be equivalent to or exceed the stated values for biological indicators. Type 5 indicators can be used to monitor a variety of steam sterilization cycles over the entire range of temperatures used in health-care facilities. Type 5 indicators are required to be tested at three stated values: 121°C (250°F) and 135°C (275°F), and at one or more equally spaced temperature points in between. The three stated values demonstrate how the chemical indicator integrates over the temperature range. However, this indicator cannot substitute for a biological indicator where required.

When manufacturers design and test their Type 5 indicators at these three stated values, they pick one set of test points at which the indicator should reach its endpoint and a second set of test points having a temperature 1°C lower and an exposure time 15 percent shorter. At these second set of test points, the indicator should not reach its endpoint, and therefore it should not show sterilization has been achieved. The fact that the second set of failing test points are closer to the stated values for which it passes makes this a very sensitive indicator. In addition, the stated value for Type 5 integrating indicators for steam must be greater than 16.5 minutes at 121°C (250°F) and greater than 1.2 minutes at 135°C (275°F).

**Type 6** chemical indicator is defined as an emulating indicator. It is similar to a Type 5 indicator, but it is specific for a defined set of temperature and time sterilization parameters for pre-vacuum steam sterilizers. Type 6 indicators cannot measure directly the cycle killing action. Furthermore, they cannot be used as the only method of assessing sterilizer function following servicing. This indicator cannot substitute for a biological indicator where required.

**Type 5** integrating indicators and **Type 6** emulating indicators provide additional information about the critical parameters of the sterilization process to help supplement the results of physical monitors and **Type 1** exposure indicators.

A pouch containing a Type 5 chemical indicator and a biological indicator should be used for dental implant loads. The more parameters that are monitored with a chemical indicator can provide the greatest assurance and serve as the basis for early load release if an emergency situation arises and you cannot wait for biological indicator results. Typically, implants must be held until the biological
indicator results are known. Implants may be released if an emergency before the biological indicator results are known; however, the biological indicator should complete incubation.

**Biological Indicators**

The CDC recommends performing biological monitoring, or spore testing, on each sterilizer at least weekly. Many sterilizers have multiple programs that can be set by the user because of the different types of loads processed in the dental office, such as individual items in pouches or wrapped cassettes containing handpieces and hollow instruments. According to the standard ANSI/AAMI ST79 Section 10.7.4.1, a biological indicator must be run with each different load type for that sterilizer. Monitoring each sterilizer’s cycle program with a biological indicator can identify an equipment malfunction or an error in packaging or placement of the items. The biological indicator should be placed at the location within the sterilizer where it is most challenging for steam to penetrate. Your sterilizer’s manual or manufacturer will help you determine this, but the test pack is typically placed on the bottom rack, in the front, over the drain. Always incubate an unsterilized biological indicator from the same lot with the sterilized biological indicator as a positive control. If you use a mail-in service, send a control with test biological indicator for each sterilizer. The unsterilized, positive control will change color due to spore germination. Record this result along with each weekly test result.

A biological indicator should be placed in every load containing implantable devices, and the implantable devices must be held until biological indicator results are confirmed negative. A positive (failing) spore test, but passing chemical indicators, may suggest operator error instead of equipment malfunction.

*(If a manufacturer provides reprocessing instructions that allow steam sterilization of its dental implant, the implant should be quarantined until results of the biological indicator are known. Otherwise, dental implants are considered as single-use devices that should not be reprocessed.)*

**Indicators used with Immediate Use Steam Sterilization (IUSS)**

Immediate use steam sterilization (IUSS) of unwrapped instruments, previously called “express cycle” or “flash” sterilization, is to be used only under specific circumstances. They may be unplanned or emergency situations or where there is an immediate need for a patient-specific item. An insufficient instrument inventory is not a satisfactory reason for IUSS. When an item is processed using IUSS, it is unpackaged, and the exposure parameters are met. However, the drying time is shortened or eliminated, and the item is used immediately; it is never stored in its unwrapped condition. Monitor these sterilization cycles by observing mechanical indicators, use a multi-parameter internal chemical indicator inside the container, and a biological indicator. If using a biological indicator that claims results can be read at an interval less than 24 hours, record the result at that time, and re-incubate the biological indicator up to 24 hours and read again.
How the items are handled post-sterilization is just as important as the sterilization process itself. The items are unwrapped, and therefore must be delivered chairside in an aseptic manner and never stored unwrapped. They will still have considerable moisture on them, meaning that contaminating microorganisms can be more easily transferred to sterile surfaces.

Recording Chemical and Biological Indicator Results

When a sterilizer is newly installed or has been repaired, a chemical indicator, including the air removal test, if applicable, and biological indicator should be processed to qualify that the sterilizer is capable of sterilizing a load. Keep results for each sterilizer in separate logs. In the event of a failure, retain the chemical indicator or photograph it to help the repair service trouble-shoot the failure. For example, the pattern on a Bowie-Dick test card can indicate the type of failure. Failures may present as a localized lack of color change in the center or a spattering or mottling pattern, for example. These symptoms indicate a specific cause, perhaps an air leak or the presence of moisture not in the form of steam. Many chemical indicators have ink that will not reverse or fade once processed, meaning you have a permanent record of the results. For cycles processed with Immediate Use Steam Sterilization (I USS), the cycle should be detailed including what items were in the load.

Table 1. Examples of Sterilization Monitoring Services

<table>
<thead>
<tr>
<th>Monitoring Service</th>
<th>Spore test results are available online</th>
<th>Notification by telephone of failed spore test</th>
<th>Accreditation/credentials for Sterilization Monitoring Service</th>
<th>Length of time in Business</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crestex International</td>
<td>Yes</td>
<td>Yes</td>
<td>None</td>
<td>Since 1985</td>
</tr>
<tr>
<td>MedTest Laboratories, Inc.</td>
<td>Not at time of publication</td>
<td>Yes</td>
<td>None</td>
<td>Since 1994</td>
</tr>
<tr>
<td>North Bay Resources, Inc.</td>
<td>Yes</td>
<td>Yes</td>
<td>registered with the FDA as a re-packages</td>
<td>Since 1999</td>
</tr>
<tr>
<td>Indiana University School of Dentistry Sterilization Monitoring Service</td>
<td>Yes</td>
<td>Yes</td>
<td>None</td>
<td>Since 1992</td>
</tr>
<tr>
<td>Loma Linda University Sterilization Assurance Service</td>
<td>Not at time of publication</td>
<td>Yes</td>
<td>None</td>
<td>Since 1992</td>
</tr>
<tr>
<td>The Ohio State University Sterilization Monitoring Service</td>
<td>Not at time of publication</td>
<td>Yes</td>
<td>None</td>
<td>Since 1962</td>
</tr>
<tr>
<td>University of Colorado School of Dental Medicine</td>
<td>Yes</td>
<td>Yes</td>
<td>None</td>
<td>Since 1993</td>
</tr>
<tr>
<td>UF Sterilization Monitoring Service &amp; Consultation Services</td>
<td>Not at time of publication</td>
<td>Yes</td>
<td>None</td>
<td>Since the early 1990s</td>
</tr>
<tr>
<td>University of Iowa Sterilization Monitoring Program</td>
<td>Yes, with email notification of email</td>
<td>Yes</td>
<td>All laboratory staff are AIAC certified / Medical Laboratory Scientists. Lab program itself is not certified</td>
<td>Since 1989</td>
</tr>
<tr>
<td>University of Kentucky Sterilization Monitoring Program</td>
<td>Not at time of publication</td>
<td>Yes</td>
<td>None</td>
<td>Since 1995</td>
</tr>
<tr>
<td>DRI SterilStar Monitoring Service</td>
<td>Yes</td>
<td>Yes</td>
<td>None</td>
<td>Since 1991</td>
</tr>
<tr>
<td>Comprehensive Dental Monitoring Services Middle Tennessee</td>
<td>Not at time of publication</td>
<td>Yes</td>
<td>None</td>
<td>Since 1987</td>
</tr>
</tbody>
</table>

|--------------------------------|----------------|----------------|

Table 2 provides monitoring service pricing at the time of printing and the corresponding annual cost of supplies for in-office monitoring. When selecting a program or purchasing supplies to perform the monitoring yourself, keep in mind that
the CDC recommends monitoring all sterilizers weekly. Your state dental board may require weekly monitoring as well. Program pricing options are per sterilizer; some services offer a discount for additional sterilizers.

### Table 2. Sterilization Monitoring Services Programs and Cost information

<table>
<thead>
<tr>
<th>Monitoring Service</th>
<th>Annual Cost of Weekly Spore Test Monitoring Service</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autoclave Testing Service, Inc.</td>
<td>$154</td>
</tr>
<tr>
<td>Crosstex International 800-810-3336 or 303-690-3556 <a href="http://www.crosstex.com">www.crosstex.com</a></td>
<td>$175 includes: 100 tests and digital recorder with 12-month shelf life.</td>
</tr>
<tr>
<td>Premium Service (upgrade included) Most frequently purchased: Autoclave Premium Test Kit contains 14 tests including 1 control strip.</td>
<td></td>
</tr>
<tr>
<td>MicroTest Laboratories, Inc. 800-713-3334 <a href="http://www.microtestlabs.com">www.microtestlabs.com</a></td>
<td>$225</td>
</tr>
<tr>
<td>North Bay Associate, LLC 800-280-7766 <a href="http://www.nba.com">www.nba.com</a></td>
<td>Basic 12 tests $200</td>
</tr>
<tr>
<td>Indiana University School of Dentistry Sterilization Monitoring Service 317-274-6411 or 317-274-5413 <a href="http://www.smis.iuuk.edu">www.smis.iuuk.edu</a></td>
<td>$375 includes: one control strip per test.</td>
</tr>
<tr>
<td>Loma Linda University Sterilization Assurance Service 909-624-7794 <a href="http://www.lluds.com/dentistry/tas">www.lluds.com/dentistry/tas</a></td>
<td>$312 includes 50 tests and results documentation.</td>
</tr>
<tr>
<td>Medical Testing Laboratories Inc. 888-476-7578 dentistry.indiana.edu</td>
<td>$375 includes: 12 tests and results documentation.</td>
</tr>
<tr>
<td>University of Colorado School of Dental Medicine 303-724-6580 <a href="http://www.ucdenver.edu">www.ucdenver.edu</a></td>
<td>$750 includes: 12 tests and results documentation.</td>
</tr>
<tr>
<td>UF Sterilization Monitoring Service &amp; Consultation Services (University of Florida) 352-273-8370 dental.ufl.edu</td>
<td>Full Service $910 includes: 12 tests and results documentation.</td>
</tr>
<tr>
<td>University of Iowa Sterilizer Monitoring Program 800-626-4962 <a href="http://www.dentistry.uiowa.edu">www.dentistry.uiowa.edu</a></td>
<td>$760 includes: 12 tests and results documentation.</td>
</tr>
<tr>
<td>University of Louisville Sterilizer Monitoring Program 800-554-9356 <a href="http://www.sternlabmonitoring.com">www.sternlabmonitoring.com</a></td>
<td>$119 includes: 12 tests and results documentation.</td>
</tr>
<tr>
<td>WM Sterilizer Monitoring University of Minnesota 612-620-0683 <a href="http://www.dentistry.umn.edu">www.dentistry.umn.edu</a></td>
<td>$290 includes: 12 tests and results documentation.</td>
</tr>
<tr>
<td>Comprehensive Dental Sterilizer Monitoring Services, Upper Midwest Dental, Texas A&amp;M Health Sciences Center 214-829-1918 <a href="mailto:Bob@bissm.com">Bob@bissm.com</a></td>
<td>$163 includes: 12 tests and results documentation.</td>
</tr>
</tbody>
</table>

* Percents rely on the spore strip and results obtained, not troubleshooting and service plans.

**The spore test design allows you to test multiple locations within a sterilizer. The CDC does not specify this test design. However, a 2-strip test can still be used, strips are placed in alternating testing every week to enhance failure detection in the same way.**

**The University of Florida basic service is a monthly option. For more information, please call or email.**

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**Examples of Commercial Sterilizer Monitoring Services Test Reports**

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**Click to enlarge view.**
Figure 3a. Autoclave Testing Service Report

Figure 3b. North Bay Bioscience Test Report
Examples of University-based Sterilizer Monitoring Services
Test Reports

![Image of Sterilization Monitoring Service Microbiology Report]

**University of Colorado-Denver School of Dental Medicine Test Report**
Table 3. Sterilization Indicator Recommendations

<table>
<thead>
<tr>
<th>Indicator Type/Class</th>
<th>Recommended Frequency</th>
<th>Placement Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 1 Chemical Indicator</td>
<td>Every load</td>
<td>Horizontally in the sterilizer chamber near the door and over the door</td>
</tr>
<tr>
<td>Type 2 Chemical Indicator</td>
<td>Every load</td>
<td>Horizontally in the sterilizer chamber near the door and over the door</td>
</tr>
<tr>
<td>Internal Chemical Indicator</td>
<td>Every load</td>
<td>Place chemical indicator in the sterilizer in such a way that it can be seen even removed from the sterilizer without opening the pack</td>
</tr>
<tr>
<td>Biological Indicator (spore test)</td>
<td>Weekly, or as required for special circumstances (i.e., implants)</td>
<td>Perform test with a full load to detect a problem with overlapping or improper packaging. Place the BI in a pouch by itself. Because it will have to incubate it, which necessitates opening the pack it's in.</td>
</tr>
</tbody>
</table>

Click to enlarge view.

The Bottom Line

- The CDC "Guidelines for Infection Control for Dental Health Care Settings" instruct dentists to use a multi-parameter internal chemical indicator that shows that each load processed was exposed to adequate levels of time, temperature and steam. These indicators are to be used with each load. Regardless of the class, chemical indicators are a presumptive indication as to whether or not sterilization was achieved, as it can be read as soon as the load is processed. A chemical indicator is not to be used in place of weekly biological monitoring (BI/spore test).

- Pre-programmed cycles can differ from one sterilizer to another. Always read the manufacturer instructions for recommended cycle time/temperature for a given type of load. The sterilizer manufacturer should provide guidance on
placement/location of biological indicators inside the sterilizer. “Cold spots” and rate of penetration will differ from one sterilizer type or model to another. The sterilizer operating manual, as well as sterilizer accessories and instrument instructions, should be available for review at all times, and reviewed annually to be sure the version is current and the instructions are followed.

- If using a two-strip test for biological monitoring, note in your sterilizer log the location of where you place the biological indicators each time they are used. The procedure for placing the strips should also be explained when training staff, and if appropriate, noted in your office manual.

- Do not use a sterilizer if a chemical or biological indicator reveals sterilization has not been attained. Troubleshoot or call the manufacturer for advice or to schedule service. Once it is repaired or other corrective action is made, run a spore test with a full test load to confirm the sterilizer is functioning properly. Do not use the contents from this test load until the spore test is read (24 hours).

- State dental boards and OSHA can inspect dental offices and records and cite violations in infection control practices. Each state dental board practice act specifies the state requirements for infection control practices in the dental office. In many cases, OSHA and state dental board regulations mirror the CDC Guidelines, but they can differ. State dental board contact information can be found here.

- Immediate use steam sterilization (IUSS/flash sterilization) should be reserved for exceptional circumstances. In these cases, both chemical and biological indicators must be used with the load. For the sterilization load processed using IUSS, a detailed results record must be kept down to the patient record in case the load fails the spore test. If you need to utilize IUSS, relying on a monitoring service is not going to be practical, since you will want the results as soon as possible. If you are going to keep supplies on hand for when IUSS is necessary, then you might want to consider performing the in-office monitoring routinely.

- It may be practical to keep sterilizer maintenance/repair log nearby. In the event of suspected malfunction, you can see when the sterilizer was last serviced. The first thing one should do after a sterilizer has been repaired is run a spore test (and Bowie-Dick test if applicable) to qualify it for operation.

- When considering using a service versus doing it yourself, keep in mind that in both cases, you process the spore strip in your sterilizer, so half the work is completed in the office. Once you buy an incubator/heating block, you will recover the cost over time.
Definitions

(Adapted from ANSI/AAMI ISO 11140-1, 2014)³

Critical process variable. For steam sterilizers, there are three critical variables: time, temperature, and moisture.

Endpoint. “The point of observed change defined by the manufacturer, occurring after the indicator has been exposed to specified stated values.” The endpoint on some chemical indicators may be a visual change, such as a color changing from yellow to black, for example. The visual change may be a progressive response to a “pass” or “accept” area upon exposure to critical process variables.

Stated value. This is the “value or values of a critical process variable at which the indicator is designed to reach its endpoint as defined by the manufacturer.” For indicator Types 3, 4, 5 and 6, the standard states that each indicator (or the label or instructions for use) must be clearly marked with the stated values.

Note: The term “class” has been replaced with “type” to describe indicators according to their intended use. Beginning in 2015, manufacturers will begin updating their products and packaging to reflect the new term “type.”

Type 1. Exposure or exposure indicator. Indicates exposure to a process to allow differentiation between an unprocessed and process items, and/or indicate gross failure of a sterilization process.

Type 2. Indicators for use in specific tests. For use in special applications (e.g. Bowie-Dick).

Type 3, 4, 5 and 6. “Internal” indicators. Placed inside individual load packaging to assess attainment of the critical process variable(s) at the point of placement.

Type 3. Single critical process variable indicator. Reacts to one critical process variable.

Type 4. Multi-critical process variable indicator. Reacts to more than one critical process variable.

Type 5. Integrating indicator. Reacts to all critical process variables.

References

1. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST55:2010 Table top steam sterilizers; 2010.
5. Kirckof S. Chemical Indicators-It's Not Just a Numbers Game; 2011.

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