

Sterilization - Monitoring

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Process Challenge Device (PCD)/Challenge Test Pack (1/16) New

Question: Is there a recommendation that we start using a PCD? If so, is there a recommendation on what to use? Should we make our own?

Answer: Yes, Biological Indicator (BI) monitoring (also called spore testing) must be done within a process challenge device (PCD) also known as a challenge test pack. A PCD is a disposable device, pack, tray or a stack of 16 surgical towels that will create a challenge for steam to reach a biological or chemical indicator (CI) placed within it. A PCD may contain a BI alone, a BI and an integrator (a class 5 CI), an integrator alone or an emulating (Class 6) CI. AF dental clinics will use integrators for all steam sterilization. Integrators cannot be used in dry heat sterilizers. For dry heat sterilizers use a single-variable CI. A PCD may be a user assembled test pack, tray, or a stack of 16 surgical towels. There are also commercially available disposable preassembled PCDs. Many clinics prefer the commercial pack, when utilizing floor size sterilizers, for ease of use. The purpose of the BI is to test the efficacy of the sterilizer and is done at least weekly, preferably daily. There is no need to place a BI (within a PCD) in every load unless each load has an implantable device or unless your local policy states you must run a BI for each load. If you have a floor size sterilizer (larger than 2 cubic feet) you can make a user assembled PCD using a 16 surgical towel method or you can purchase a preassembled disposable PCD. If you have a table top sterilizer you can use the most difficult to sterilize pack /tray that is routinely processed, as your PCD.



Selected References

- Cuny E. The use of a process challenge device in dental office gravity displacement tabletop sterilizers. American Journal of Infection Control 2015; 43:1131-1133
- Association for the Advancement of Medical Instrumentation, American National Standards Institute. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST79:2010/A12010/A22011/A32012/A42013. Arlington, VA: Association for the Advancement of Medical Instrumentation, Consolidated Text 2014.
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Process Challenge Device (PCD) with an Integrator Only (1/16) New

Question: Do USAF dental clinics have to use a PCD/challenge test pack containing an integrator (Class 5 CI) in each load? We are already placing an integrator in each kit and pack so why do we need an additional integrator within a PCD?

Answer: Yes, a new initiative was introduced Jan 2016 for USAF dental clinics to have a PCD/challenge test pack containing an integrator in each load. The reason AF dental clinics are adopting the practice of an additional integrator within a PCD is because the integrator test pack provides a greater challenge to the sterilization process and also provides an additional CI that can be attached to the Load Release Document (Attachment 2 *USAF Guidelines for Infection Prevention & Control in Dentistry* 2016) and retained as part of the sterilization records. Remember that sterilizers larger than 2 cubic feet (e.g. floor size models) require user assembled PCD/test packs (using a 16 surgical towel technique) or a commercially assembled disposable type of PCD/test pack. If you are using a table top sterilizer your user assembled PCD can be the most difficult to sterilize pack/kit that you routinely process.

Selected References

- Cuny E. The use of a process challenge device in dental office gravity displacement tabletop sterilizers. *American Journal of Infection Control* 2015; 43:1131-1133
- Association for the Advancement of Medical Instrumentation, American National Standards Institute. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST79:2010/A12010/A22011/A32012/A42013. Arlington, VA: Association for the Advancement of Medical Instrumentation, Consolidated Text 2014.
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Routine Sterilizer Monitoring (1/16) New

Question: Is there certain monitoring we should do for the sterilizer to make sure it runs properly?

Answer: Yes, the regular monitoring that is done to verify sterilizer efficacy includes the following:

1. Physical monitoring

Physical monitoring involves examining and recording the critical variables (time, temperature and pressure). Physical monitoring provides real time assessment of each cycle. This information is found on the sterilizer print out or on the digital display. If your machine does not have a print-out, contact the manufacturer. It is possible that your machine has print-out capabilities and the manufacture can provide equipment for print-outs. At the end of each cycle, before items are removed from the sterilizer, review the print-out to ensure that the correct time, temperature, and pressure (TTP) were achieved and then initial the print-out once all of these have been verified.

TTP

Did you check me?

2. External and Internal Chemical Indicator (CI) Monitoring of Packages

Monitoring CIs can help detect sterilization process failures immediately. Failures can be due to incorrect packaging or loading or due to sterilizer malfunctions. Remember that if a CI reacts to a one or more critical variable (time, temperature or pressure), and shows a “pass” response, this does not prove that an item is sterile. Monitoring CIs is only one part of quality assurance and must be done in conjunction with monitoring physical indicators, biological indicator (BI) monitoring and other monitoring ([Click here](#) for additional information about external and internal indicators).

3. Biological Indicator (BI) Monitoring

BIs must be used within PCDs at least weekly, preferably daily for routine sterilizer monitoring. Additionally they must be part of routine load release criteria for every load that contains implantable devices ([Click here](#) for additional information about BIs).

4. Bowie-Dick Testing (e.g. Daily Air removal Testing [DART])

Daily air removal testing is for pre-vacuum steam sterilizers only. These tests must be performed in an empty chamber and remember that a warm-up cycle precedes the daily air removal test. Do not preform the test in a cold chamber. A cold chamber may cause the air removal test to fail. If the test fails, follow the manufacturer IFU. Many manufacturers recommend conducting two more tests in the

event of a failure (test #2 and test #3). If both test #2 and #3 pass you can continue. If test #2 or #3 fails you must contact the manufacturer or Biomedical Equipment Technicians (BMETs).

Selected References

- Association for the Advancement of Medical Instrumentation, American National Standards Institute. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST79:2010/A12010/A22011/A32012/A42013. Arlington, VA: Association for the Advancement of Medical Instrumentation, Consolidated Text 2014.
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Load Release Document (1/16) New

Question: I heard there is a new document that Air Force dental clinics must complete before releasing sterilized loads, is this true?

Answer: Yes, there is a Load Release Document that is being piloted in AF dental clinics before mass release. It will be completed after a load of instruments has been sterilized and before the instruments are stored. The criteria for routine load release are the following:

1. Physical monitoring of each cycle
2. External and internal chemical indicator monitoring of the kits/packages
3. A Process Challenge Device (PCD) containing an integrator for each cycle (New AF initiative).
4. Biological indicator monitoring for each load containing implantable devices (dental implants should be received sterile and are single use/disposable, therefore there should be no need to sterilize implants in AF dental clinics)

The Load Release Document (Attachment 2 *USAF Guidelines for Infection Prevention & Control in Dentistry 2016 [update in progress]*) will require documentation of the physical monitoring, external and internal chemical indicator (CI) monitoring of packages, biological indicator (BI) monitoring, and Bowie Dick testing for Pre-vacuum sterilizers (e.g. Daily Air Removal Test). The document will also have a place to affix the load sticker and the integrator (Class 5 CI) from the PCD/challenge test pack.

Selected References

- Cuny E. The use of a process challenge device in dental office gravity displacement tabletop sterilizers. *American Journal of Infection Control* 2015; 43:1131-1133
- Association for the Advancement of Medical Instrumentation, American National Standards Institute. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST79:2010/A12010/A22011/A32012/A42013. Arlington, VA: Association for the Advancement of Medical Instrumentation, Consolidated Text 2014.
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Maintaining Sterilization Records (5/08) Updated (1/16)

Question: How long should I keep sterilizer biological indicator (BI) results (spore test results)? What other types of documentation should I maintain in the sterilization log?

Answer: According to the USAF Infection Control Guidelines for Dentistry, sterilization monitoring results must be maintained for a period dictated by local statutes and Medical Treatment Facility (MTF) policy or two years, whichever is longer.



Minimum documentation for a sterilization quality assurance program includes:

1. sterilizer identification number;
2. date and time of test;
3. sterilizing conditions — temperature and exposure period, (automated printout);
4. load contents (e.g., type of instrument sets [e.g., using local terminology/abbreviations such as prophylaxis, operative, surgery])
5. name of individual conducting the test;
6. results of the test and control; and
7. nature and date of any malfunctions or repairs.

Sterilization monitoring records are a component of an overall dental infection-control program and provide evidence of the clinic's quality control program. Maintaining accurate records ensures cycle variables have been met and establishes accountability. Additionally, in the event of a problem with a sterilizer (e.g., unchanged chemical indicator [CI], positive biological indicator [BI]) documentation helps individuals determine if a recall is necessary. Documenting the load contents will facilitate the recall process in the event of a sterilization failure.

USAF dental clinics will use a Load Release Document (Attachment 2 in USAF Guidelines for Infection Prevention & Control in Dentistry 2016). This document will be piloted before mass release.

Selected References

- Association for the Advancement of Medical Instrumentation, American National Standards Institute. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST79:2010/A12010/A22011/A32012/A42013. Arlington, VA: Association for the Advancement of Medical Instrumentation, Consolidated Text 2014.
- CDC. Guidelines for infection control in dental health-care settings – 2003. MMWR 2003; 52(No. RR-17):1–66.
- Harte JA, Molinari JA. Sterilization procedures and monitoring. In: Molinari JA, Harte JA eds. *Cottone's Practical Infection Control in Dentistry*, 3rd ed. Baltimore: Lippincott Williams & Wilkins, 2009:148–170.
- USAF Guidelines for Infection Prevention & Control in Dentistry.

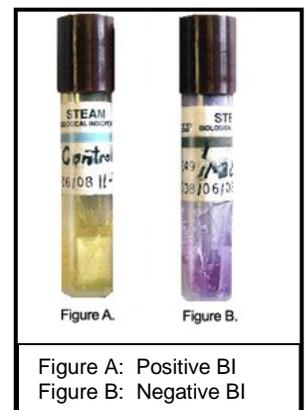
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Disposal of Biological Indicators (BI) (5/08) Updated (1/16)

Question: What is the procedure for disposing of used biological indicators (BIs) (i.e., spore tests)?

Answer: Review the manufacturer instructions for use (IFU) for your product. The IFU should cover disposal issues. Generally, negative spore tests (i.e., no growth) can be disposed of as normal waste. However, it is usually recommended to autoclave positive spore tests or those that exhibit growth, such as the controls, at 250°F/121°C for at least 30 minutes before disposal. If local policy permits, an alternative would be to dispose of the controls or any other positive tests with your regulated/biohazardous waste (e.g., red bag).

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External and Internal Chemical Indicators (CIs) (10/09) Updated (1/16)

Question: What is the difference between external and internal chemical indicators (CIs)? What are single- variable, multi-variable and integrating chemical indicators (CIs)?

Answer: External, or process Chemical Indicators (CIs) are applied to the outside of a package and include such things as CI tape or special markings on the package. When a certain temperature is reached, the color of the CI rapidly changes color. External CIs do not guarantee that sterilization has

been achieved or even that a complete sterilization cycle has occurred. Some external CIs change color long before proper sterilization conditions are even met. "Autoclave" tape is an example of an external CI that can be problematic at times because it often changes to show the striped pattern following just a brief exposure to steam. External CIs are primarily used to identify whether or not packages have been processed through a heat sterilizer. This can help prevent the accidental use of non-sterile items.

Internal CIs react more slowly to the sterilization critical variables (time, temperature and pressure) than external CIs and can help detect sterilizer failures that may result from incorrect packaging, improper sterilizer loading, or malfunctions of the sterilizer. Internal CIs can be single-variable, multi-variable, integrating or emulating CIs. A single-variable CI responds to one of the critical variables of sterilization at a stated value (e.g., heat), while a multi-variable indicator is designed to react to two or more variables at a stated value (e.g., time and temperature). Integrating CIs also known as integrators respond to all critical variables of sterilization with stated values being equal to or exceeding the performance requirements for biological indicators. Emulating CIs react to all critical variables at stated values for specific sterilization cycles. Because integrating, and emulating CIs provide more information about the sterilization cycle, they can provide a more reliable indication that sterilization conditions have been met. (multi-variable, integrating and emulating CIs are available for steam sterilizers (i.e., autoclaves). An internal CI is placed in every package to evaluate whether the instruments were exposed to the sterilization conditions. In other words, internal CIs should be used inside each package to ensure that the sterilizing agent (steam) has penetrated the packaging material and actually reached the instruments inside. An external CI (e.g., chemical indicator tape) should be used when the internal CI cannot be seen from outside the package.



External CI



Selected References

- Association for the Advancement of Medical Instrumentation, American National Standards Institute. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST79:2010/A12010/A22011/A32012/A42013. Arlington, VA: Association for the Advancement of Medical Instrumentation, Consolidated Text 2014.
- CDC. Guidelines for infection control in dental health-care settings – 2003. MMWR 2003; 52(No. RR-17):1–66.
- Harte JA, Molinari JA. Sterilization procedures and monitoring. In: Molinari JA, Harte JA eds. *Cottone's Practical Infection Control in Dentistry*, 3rd ed. Baltimore: Lippincott Williams & Wilkins, 2009:148–170.
- USAF Guidelines for Infection Prevention & Control in Dentistry.

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Biological Indicator Monitoring Frequency (3/09) Updated (1/16)

Question: Our medical treatment facility (MTF) infection Preventionist (IP) wants the dental clinic to do monitoring with a biological indicator every instrument load? Has the policy for frequency of monitoring with a BI changed?



Answer: Current published infection-control and sterilization standards and guidelines do not support using biological indicators (BIs) every load unless you are sterilizing an implantable device or using flash sterilization which in dental clinics are extremely rare situations. The *USAF Guidelines for*



Infection Prevention & Control in Dentistry are consistent with published national standards and guidelines, which recommend at least weekly and preferably daily monitoring of sterilizers using a BI. As a reminder, USAF dental facilities may have to use BIs daily if required by MTF policy. However, if dental facilities are requested to do BI monitoring more frequently than daily, they are encouraged to use the *USAF Guidelines for Infection Prevention & Control in Dentistry and AAMI ST79 10.5* as a reference when discussing sterilization monitoring with their MTF IPs or with inspectors. Several references providing recommendations on the use of biological indicators have been updated in this document; however the recommendation on frequency of use did not change. For a list of recommendations, [click here](#).

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Biological Indicators (BI) and Instrument Processing Monitoring (3/09) Updated (1/16)

Question: How often should biological indicators be used to monitor sterilizer equipment? Besides BI monitoring of sterilizers, what other forms of Instrument processing monitoring are recommended?

Answer: Biological indicators (BIs) (spore test), are just one method for monitoring the sterilization process. Biological monitoring assesses the sterilization process by killing known highly resistant microorganisms (e.g., *Geobacillus* or *Bacillus* species). However, biological monitoring of the sterilizer

is performed periodically (e.g., once a week, once a day) and the results are not obtained immediately. It is important to remember that there is more to a sterility assurance program than just BI monitoring of the sterilizers. Physical (mechanical) and chemical indicators (CIs) are important to monitor as well. They can help detect procedural errors and equipment malfunctions immediately. Because the results of physical (mechanical) monitoring (e.g., assessing cycle time, temperature, and pressure) can be observed during the sterilization cycle this might be the first indication of a problem. Chemical monitoring results are obtained immediately following the sterilization cycle and therefore can provide more timely information about the sterilization cycle than a BI. A CI must be placed in every package, and if not visible from the outside of the package, an external CI must be used. Chemical indicators help manage and maintain clear separation of processed and nonprocessed items, helping to prevent the possibility of using nonprocessed instruments.



The *USAF Guidelines for Infection Prevention & Control in Dentistry* recommend at least weekly preferably daily use of biological indicators (i.e., spore tests) and more frequent testing if directed by MTF policy. This recommendation is consistent with published standards and guidelines ([Table 1](#)) which recommend at least weekly preferably daily biological monitoring of sterilizers. A biological indicator (BI) must be used within a process challenge device (PCD) for each sterilizer load containing an implant (dental implants should come from the manufacturer sterilized and are single use, therefore there should be no need to re-sterilize dental implants). Because of the rapid turnover of dental instruments, daily BI monitoring offers the advantage of less complex recall procedures in the event of a sterilization failure. Because USAF dental clinics are part of the Medical

Treatment Facility (MTF), consistency between procedures in the dental clinic and the medical clinic or hospital is indicated. Most medical facilities, especially those with an operating room and in-patient facilities perform biological monitoring of sterilizers daily, therefore the dental clinics would be required to perform daily BI monitoring.

As a reminder, dental infection control operating instructions must be coordinated with and reviewed by the local MTF infection control officer before implementation, therefore the opportunity exists for changes in the frequency of biological indicator use within the dental clinic to ensure consistency throughout the

MTF. Dental facilities are encouraged to use this information as a reference when discussing sterilization monitoring within their MTFs or with inspectors.

Table 1: Routine Use of Biological Indicators (Spore Tests)

Organization	Reference	Recommendation
Centers for Disease Control and Prevention	CDC. Guidelines for infection control in dental health-care settings – 2003. MMWR 2003; 52(No. RR-17).	"Monitor sterilizers at least weekly by using a biological indicator with a matching control (i.e., biological indicator and control from same lot number)"
Centers for Disease Control and Prevention	Rutala WA, Weber DJ, and the Healthcare Infection Control Practices Advisory Committee. Guideline for disinfection and sterilization in healthcare facilities, 2008:1–158.	"Use biologic indicators to monitor the effectiveness of sterilizers at least weekly with an FDA-cleared commercial preparation of spores intended specifically for the type and cycle variables of the sterilizer."
Association for the Advancement of Medical Instrumentation	Association for the Advancement of Medical Instrumentation, American National Standards Institute. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST79-2006 and ANSI/AAMI/A1:2008. Arlington, VA: Association for the Advancement of Medical Instrumentation, 2008.	"Biological indicators should be used within process challenge devices for routine sterilizer efficacy monitoring at least weekly, but preferably every day that the sterilizer is in use."
American Dental Association	American Dental Association's Council on Scientific Affairs and Council on Dental Practice. Infection control recommendations for the dental office and the dental laboratory. J Am Dent Assoc 1996;127:672–80. (In March 2004 the ADA decided not to publish a separate set of dental infection-control guidelines and encouraged all dental health-care personnel to follow appropriate infection-control procedures as described in the 2003 CDC guidelines.)	"Biological monitors should be used routinely to verify the adequacy of sterilization cycles. Weekly verification should be adequate for most dental practices."
<i>References for Historical Purposes</i>		
Centers for Disease Control and Prevention	Garner JS, Favero MS. CDC guideline for handwashing and hospital environmental control, 1985. Infect Control 1986;7:231–43.	"All sterilizers should be monitored at least once a week with commercial preparations of spores intended specifically for the type of sterilizer."
Centers for Disease Control and Prevention	CDC. Recommended infection-control practices for dentistry, 1993. MMWR 1993;42(No. RR-8).	"Proper functioning of sterilization cycles should be verified by the periodic use (at least weekly) of biologic indicators (i.e., spore tests)."
Centers for Disease Control and Prevention	CDC. Recommended infection-control practices for dentistry. MMWR 1986;35:237–42.	"The adequacy of sterilization cycles should be verified by the periodic use of spore-testing devices (e.g., weekly for most dental practices)."

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Question: Are there any new advances in biological monitoring, such as a test that provides results in a timelier manner than two days?

Answer: Traditionally, a biological indicator (BI), or spore test, required up to seven days of incubation to detect viable spores. A new generation of tests, now provides results in one to three hours for gravity or pre-vacuum steam sterilizers when incubated in a special auto-reader incubator. These rapid-readout BIs should not be confused with enzyme tablets or integrating chemical indicators (CIs), or items labeled with the statement “equivalent to biological indicators” (or similar wording). In contrast to integrators, rapid-readout BIs contain spores and meet the requirements of a biological indicator.



The manufacturer recommendations must be followed for the rapid-readout BI and routine physical (e.g., checking the temperature, time, and pressure) and chemical monitoring (e.g., using internal and external indicators) must also be performed. After the initial incubation (i.e., 1 or 3 hour reading) in the special auto-reader, the performance of the sterilization process must be periodically verified on at least a weekly basis, including the use of a control BI. Follow the manufacturer or MTF policy regarding periodic verification of the early readout results. The periodic verification may be either continued incubation of the rapid-readout BI (according to manufacturer instructions) or by using a conventional BI. If conventional biological indicators will be used in these instances, maintain a conventional incubator in the facility. Using rapid readout BIs daily, along with physical (mechanical) and chemical indicators, offers the advantage of less complex recall procedures in the event of a sterilization failure.

Selected References

- Association for the Advancement of Medical Instrumentation, American National Standards Institute. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST79:2010/A12010/A22011/A32012/A42013. Arlington, VA: Association for the Advancement of Medical Instrumentation, Consolidated Text 2014.
- USAF Guidelines for Infection Prevention & Control in Dentistry.

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