

Troubleshooting Steam Sterilization Process Failures

—A SERIES OF UNFORTUNATE EVENTS

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Objectives

After completion of this self-study activity, the learner will be able to:

1. Identify a steam sterilization process failure by the use of monitoring tools.
2. List 10 of the most common reasons for steam sterilization process failures.
3. Ask five questions in order to identify clues about why there was a steam sterilization failure.
4. Test the efficacy of a steam sterilizer to return into routine use.

Test Questions

True or False

1. Packs should be used if the external chemical indicator or the internal chemical indicator has not reached its end point result (reject or incomplete color change).
2. A positive biological indicator initiates a recall of all packages processed since the last negative biological indicator.
3. Usually there is only one cause for a steam sterilization process failure.
4. Look for the obvious reasons first when trying to determine the cause for a steam sterilization process failure.
5. Sterilizer efficacy testing is done in three consecutive full sterilization cycles to verify the sterilizer is functioning.
6. Human errors such as using the wrong cycle time for the load, inappropriate packaging and loading techniques can cause steam sterilization process failures.
7. A steam sterilization cycle does not need to have the correct temperature, time and steam quality for a sterilization process to be effective.
8. An electronic record-keeping system may provide monitoring data and other information about the sterilization load to assist in determining the reason for a steam sterilization process failure.
9. Running the wrong biological indicator test pack or process challenge device in the load can create too great of a challenge for the sterilization process and result in a positive biological indicator.
10. Corrective action may include inservicing, sterilizer repair or correction of the steam supply.

Many thanks to the team at 3M Health Care for working with Managing Infection Control to provide the following accredited course. IAHCSSMM has awarded 1 contact point for completion of this continuing education lesson toward IAHCSSMM recertification. The CBSPD has pre-approved this inservice for 1 contact hour for a period of five (5) years from the date of publication. This inservice is approved by the California Board of Registered Nurses, CEP 5770 for 1 contact hour. This form is valid up to five years from the date of publication. Instructions for submitting results are on page 92.

Managing Infection Control and 3M Health Care will be working collaboratively to provide continuing education courses in monthly editions of Managing Infection Control.

Introduction

Steam sterilization process failures are the result of a series of unfortunate events. The causes for these failures may be complex and in some cases difficult to determine. Steam sterilization process failures are identified by observing the available monitoring tools. These include both the physical monitors on the steam sterilizer and the results of various types of indicators such as the Bowie-Dick (BD) tests, external chemical indicators, the Class 5 integrating indicator (Class 5 CI) in a test pack or process challenge device (PCD), biological indicator (BIs) in a test pack/process challenge device (PCD) or internal chemical indicators (CIs) used inside each package.

Each of these monitoring tools provides different information or clues about the effectiveness of the sterilization process. Not all of the tools may detect a failure at the same time, but do not ignore any clue that suggests a problem with the process because the purpose of these tools is to detect failures. When these tools indicate a steam sterilization failure, the next steps are to determine the cause for the failure by asking the right questions, correcting the failure, and retesting the sterilizer (sterilizer efficacy testing) according to the Association for the Advancement of Medical Instrumentation (AAMI) Recommended Practices so it can be placed back into routine use. Now put on your Sherlock Holmes Hat, find your magnifying glass, and learn how the expert authors look for clues as to the cause of a sterilization process failure.

Monitoring Tools

The AAMI steam sterilization recommended practices describe how to use physical, chemical and biological monitors on a routine basis in order to determine the

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Figure 1: Checklist for Identifying Steam Sterilization Process Failure

<p>Human Errors</p> <ul style="list-style-type: none"><input type="checkbox"/> Incorrect use and interpretation of monitoring tools<ul style="list-style-type: none"><input type="checkbox"/> Not determining that the physical monitors were correct for the load<input type="checkbox"/> Not identifying that the incorrect cycle was run for the load contents<input type="checkbox"/> Using the wrong BI or test pack/PCD for the load<input type="checkbox"/> Using the wrong Class 5 integrating indicator test pack/PCD used for the load<input type="checkbox"/> Not following the BI test pack/PCD or Class 5 integrating indicator instructions for use<input type="checkbox"/> Incorrect reading of Class 5 integrating indicator or BI result<input type="checkbox"/> Using the wrong internal chemical indicator for the cycle<input type="checkbox"/> Incorrect reading of internal chemical indicator<input type="checkbox"/> Incorrect storage of any chemical or biological indicators<input type="checkbox"/> Improper cycle for the load contents<ul style="list-style-type: none"><input type="checkbox"/> Not following the container or instrument/ container manufacturers instructions for use<input type="checkbox"/> Not verifying instrument/container manufactures sterilization parameters for use in your sterilizers using AAMI product testing protocol.^{1,2,3}<input type="checkbox"/> Inappropriate packaging materials or packaging technique<ul style="list-style-type: none"><input type="checkbox"/> Incorrect packing or container system for the cycle parameters<input type="checkbox"/> Not correctly preparing the container for use (i.e., filters and valves or appropriate bottom tray)<input type="checkbox"/> Using a peel pouch, woven or non-woven wrap, or towel in a gravity 270°F to 275°F (132°C to 135°C), three-minute cycle<input type="checkbox"/> Not using a mesh bottom perforated tray that allows air removal and steam penetration<input type="checkbox"/> Placing a folded peel pouch inside another peel pouch<input type="checkbox"/> Preparing textile packs that are too dense to sterilize in the cycle parameters chosen<input type="checkbox"/> Not placing basins in same direction<input type="checkbox"/> Not using non-linting absorbent material between nested basins<input type="checkbox"/> Using canisters with closed lids<input type="checkbox"/> Not disassembling or opening hinged instruments or surgical supplies	<ul style="list-style-type: none"><input type="checkbox"/> Not holding packaging materials at 68°F-73°F (20°C-23°C), 30-60% RH for two hours prior to use<input type="checkbox"/> Sterilizer loading<ul style="list-style-type: none"><input type="checkbox"/> Stacking containers systems if not recommended by manufacturer<input type="checkbox"/> Stacking perforated instrument trays<input type="checkbox"/> Not laying instrument trays flat or parallel to the shelf<input type="checkbox"/> Laying peel pouches flat instead of on edge, not properly spaced or with plastic sides not facing one direction<input type="checkbox"/> Not placing basins on edge<input type="checkbox"/> Not placing fabric packs on edge<input type="checkbox"/> Placing packages too close to each other impeding air removal and sterilant penetration around and through load <p>Poor Steam Quality or Quantity</p> <p>Wet steam</p> <ul style="list-style-type: none"><input type="checkbox"/> Improperly insulated steam lines<input type="checkbox"/> Malfunctioning trap in steam line<input type="checkbox"/> Malfunctioning or no drain check valve<input type="checkbox"/> Steam contact with a cold load<input type="checkbox"/> Steam pressure too high for the temperature<input type="checkbox"/> Too much water in steam produced at boiler (dryness should be between 97% and 100%) <p>Superheated steam</p> <ul style="list-style-type: none"><input type="checkbox"/> Improper chamber heat up<input type="checkbox"/> Desiccated packaging materials (e.g., towels)<input type="checkbox"/> Steam pressure too low for the temperature<input type="checkbox"/> Excessive reduction of steam pressure too close to sterilizer<input type="checkbox"/> Faulty steam control valve<input type="checkbox"/> Faulty pressure reducer control valve <p>Other reasons</p> <ul style="list-style-type: none"><input type="checkbox"/> Variations in steam pressure due to clogged filter, poorly engineered piping or excessive demands<input type="checkbox"/> Pressure gauges and controllers out of calibration<input type="checkbox"/> Clogged steam lines<input type="checkbox"/> Clogged steam supply strainer<input type="checkbox"/> Clogged chamber drain line, strainer or chamber drain screen<input type="checkbox"/> Malfunctioning valves<input type="checkbox"/> Noncondensable gas level >3.5% by volume
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Incomplete Air Removal

- Inadequate vacuum or vacuum depth or other air removal system
- Clogged chamber drain line, strainer or chamber drain screen
- Clogged vent lines
- Leak caused by a faulty door gasket
- Leak in other areas of chamber
- Plugged, faulty or maladjusted control valves (i.e., air break valve)
- Low steam pressure
- Low water pressure
- Too high water temperature
- Inadequate water supply pressure
- Clogged water supply strainer
- Air trapped by the load
- Incorrect cycle parameters for the load

Inadequate Cycle Temperature

- Temperature gauge out of calibration
- Long heat-up time of large loads (i.e., heat lag)
- Clogged chamber drain line, strainer or chamber drain screen
- Variations in steam pressure due to clogged filter, poorly engineered piping or excessive demands on the steam supply
- Presence of non-condensable gases in steam line and load
- Inadequate steam supply pressure
- Clogged steam supply strainer

Insufficient Time at Temperature

- Control timer out of calibration
- Inappropriate cycle parameters for the load being processed
- Come up time less than 1.5 minutes in a gravity 270°F to 275°F (132°C to 135°C) 3 minute cycle
- Oversized load

effectiveness of a sterilization process failure.^{1,2,3} All monitoring tools must have the appropriate results for the load to be released. The AAMI documents state that loads should not be released for use if the following monitoring tools indicate a sterilization process failure:

- ▶ Physical monitors on the sterilizer itself, show the correct cycle conditions were not met (e.g., time, temperature, pressure, vacuum) or that the incorrect cycle was chosen for the load;
- ▶ External chemical indicator suggests that the packages were not exposed to the physical conditions present in the steam sterilizer;
- ▶ Class 5 integrating indicator in a test pack/PCD used in loads not containing implants shows an incomplete end point result (reject or incomplete color change);
- ▶ Biological indicator (BI) in a test pack/PCD is positive.

Packs should not be used upon opening if:

- ▶ Internal chemical indicator suggests inadequate steam processing.

If a load is released prior to the results of a BI and the BI indicates a sterilization process failure (e.g., is positive), then all items processed since the last load showing a negative BI should be considered non-sterile, retrieved and reprocessed.^{1,2,3} This is called a recall.

Monitoring more frequently with a BI and obtaining results within a minimal incubation time (e.g., one or three hours) allows sterilization process failures to be identified much sooner, instruments to be turned around faster, costs associated with inventory and recall to be reduced and patient outcomes to be improved.⁴

Causes for Steam Sterilization Process Failures

There may be multiple causes for steam sterilization process failures. Human error can be the root cause as often as a malfunctioning steam sterilizer and other steam-related issues. Use the check list for steam sterilization process failures in Figure 1 to help identify the causes of the failure that occurred in your healthcare facility. This is not all inclusive but does represent a majority of the causes for steam sterilization process failures. (See Figure 1 on page 84 & 86)

Determine the Causes for the Steam Sterilization Process Failure

When a steam sterilization failure is identified by one of the monitoring tools, the first questions asked may be, *what is wrong with the monitoring tools or the steam sterilizer?* The objective of the monitoring tools is to detect sterilization process failures so pay attention to the clues they provide. The causes for a steam sterilization process failure may be complex and in some cases transient making them difficult to identify. There are many variables to analyze and often multiple variables are involved. It is important to determine all possible causes for the sterilization process failure so that each can be eliminated and the process improved.

Look for the most obvious causes first. If the monitoring tools (physical monitors and/or Class 5 integrating indicator test pack/PCD and/or BI test pack/PCD), suggest a failure with the entire load, the first step is to perform the AAMI sterilizer efficacy testing to obtain more monitoring data and verify that a sterilizer failure has occurred before calling a service representative.

Sterilizer Efficacy Testing

For 270°F to 275°F (132°C to 135°C) dynamic-air-removal sterilizer (e.g., prevacuum or positive-flush pressure-pulse), run a warm-up cycle followed by three consecutive Bowie-Dick (BD) test cycles, one right after the other in an empty chamber (determine from the sterilizer manufacture if a BD test is required). This testing should be followed by three consecutive BI test packs/PCDs, run one right after the other, in an empty chamber.¹

For other cycles that show a sterilization process failure (e.g., 270°F to 275°F [132°C to 135°C] or 250°F [121°C] gravity cycles), the same three consecutive empty cycle BI testing should be done using an appropriate BI test pack/PCD. If a transfer cart is used, cool the cart between each cycle to ensure that superheating does not occur.^{1,2,3}

If the sterilizer efficacy testing suggests a sterilizer problem, contact the appropriate service representative. It is important to remember that the failures may not be directly the result of the sterilizer but may be caused by the steam quality and quantity or water pressure or temperature supplied

to the sterilizer. The service representative may not have the equipment or skills needed to identify steam quality problems so a steam investigation service may be needed.

If the sterilizer efficacy testing does not indicate a sterilizer problem, i.e., the BD results are a pass and the BIs are negative, then there is no reason to call the service representative at this time but it is important to determine what could have changed or was different in this load to cause a failure. So let's examine the reasons for steam sterilization process failures.

Questions to Ask/Analyzing the Clues

Now it is time to start asking questions and analyzing the clues. Record keeping supplies many clues. A computerized or electronic record keeping system can simplify the assessment of sterilization process monitoring information in the event of a failure.⁶ With this system, you may be able to identify items in the failure load, review the various types of monitoring data, other loads from a specific sterilizer, and all loads recently processed by a particular operator. An electronic system may also connect to sterilizer maintenance records for a specific sterilizer that may be linked to a previous sterilization process failure with the reason for the failure, the resolution and also the results of retesting of the sterilizer.⁶ See Figure 2 for questions to ask in order to identify some clues for analyzing the problem.

Don't get discouraged if you do not identify the cause for the failure. Sometimes you need to collect more data by increasing your BI monitoring frequency to each load to see how much variation you have in the process. Sometimes you may never identify the cause for the failure. Sometimes solenoid valves malfunction intermittently causing air to leak into the chamber. Fluctuations in steam supply and water pressure and temperature are often temporary. And of course there is that human error.

It's much easier to identify failures when they happen more often because there is more information to analyze.

Correct the Failure

Once the causes for the failure are determined or the investigation is complete, take corrective action. This could include inservicing personnel on correct usage and reading of monitoring tools, correct packaging and loading procedures, increasing cycle times for the load contents, sterilizer repair,

Figure 2
Questions to Ask When a Steam Sterilization Process Failure Occurs

Review the history of previous BI positives from record keeping.

- ▶ When, why and who was involved in the last steam sterilization failures?
- ▶ What were the reasons for the previous failure?
- ▶ Was it the same sterilizer, same operator, same load?
- ▶ Were the monitoring results the same this time?

What were the results of the monitoring tools (physical, BD, external and internal CIs and BIs) from the load prior to and after the identified sterilization process failure?

- ▶ What is different about this load from the load prior to and after?

Was the failure in one or all sterilizers?

- ▶ If all sterilizers or several show a failure, what may have changed with the steam and water supply?
- ▶ Are all the sterilizers showing the problem on the same steam line?
- ▶ Are the sterilizers in different locations within the hospital?
- ▶ If one sterilizer shows a failure, where is it on the steam line?
- ▶ Are the chamber drain strainers or screens cleaned daily?
- ▶ Is the steam supply strainer clean?
- ▶ Is the water supply strainer clean?
- ▶ Is the air filter clean?
- ▶ Is there any debris inside the sterilizers?
- ▶ When was preventative maintenance done for the sterilizers in question and what did they do?
- ▶ When was repair work done on the sterilizers in question and what was done?
- ▶ When were the steam traps last inspected, cleaned or repaired?
- ▶ Is the steam supply on?
- ▶ Is the steam pressure consistent 24 hours a day?
- ▶ Is the water supply turned on?
- ▶ Is the water pressure adequate?
- ▶ Is the water pressure and temperature consistent throughout the day?
- ▶ Has there been a recent change over to an alternative boiler?
- ▶ How many sterilizers were running at the same time?
- ▶ What was the facility steam demand when the failure occurred?
- ▶ Is there any construction at the hospital that could affect the steam or water lines?

- ▶ Any other reasons for fluctuations in steam lines?
- ▶ What percentage of non-condensable gases do you have in the steam?
- ▶ Has the percentage of non-condensable gases changed in the steam?
- ▶ Is the compressed air turned on?
- ▶ Is the compressed air pressure adequate?

Did the sterilizer reach temperature with the correct steam pressure for the correct amount of time with deep enough vacuums to remove air?

- ▶ Did you compare the printouts from the failures with printouts from other loads that did not show failures to see if anything is different?
- ▶ Was the come-up time shorter or longer than usual?
- ▶ Was the time needed to pull each vacuum pulse as expected or different from loads without failures?
- ▶ Was the vacuum depth as expected or different from loads without failures?
- ▶ Does the steam pressure match the temperature (see Table 1 on page 92: Saturated Steam Is Assured When the Temperature and Pressure Have the Following Relationship).

Are you correctly running your BD test pack/PCD so you are detecting failures with the equipment?

- ▶ Did you run a warm up cycle right before the BD test pack/PCD is run?
- ▶ Did you place the BD test pack/PCD on the bottom shelf over the drain and not on the floor of the chamber or rail?
- ▶ Did you only run one BD test pack/PCD in the load and not two BD test packs/PCDs or one BD pack and one BI test pack/PCD?
- ▶ Did you follow manufacturer's time and temperature instructions for use?
- ▶ Do all personnel know how to read the result?
- ▶ Did you run a vacuum leak test?

Did you run the correct BI and/or Class 5 integrating indicator test pack/PCD for the type of sterilizer and load parameters?

- ▶ Did you follow the BI or BI test pack/PCD instructions for use?
- ▶ Do you store the BI or BI test pack/PCD according to manufacturer's instructions?
- ▶ Do all personnel know how to handle and incubate the BI and read BI results?
- ▶ Did you follow the Class 5 integrating indicator test pack/PCD instructions for use?
- ▶ Do you store the Class 5 integrating indicator according to manufacturer's instructions?
- ▶ Do all personnel know how to read the Class 5 integrating indicator results?

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Sterile Process and Distribution CEU Information

CEU Applicant Name _____
 Address _____
 City _____
 State _____ Zip Code _____

The CBSPD (Certification Board for Sterile Processing and Distribution) has pre-approved this inservice for one (1) contact hour for a period of five (5) years from the date of publication. Successful completion of the lesson and post test must be documented by facility management and those records maintained by the individuals until re-certification is required. **DO NOT SEND LESSON OR TEST TO CBSPD.**

For additional information regarding CBSPD certification, contact: CBSPD, 121 State Hwy 31N, Suite 500, Flemington, NJ 08822 or call (908) 788-3847 or visit www.sterileprocessing.org.

IAHCSMM has awarded 1 Contact Points for completion of this continuing education lesson toward IAHCSMM recertification.

Nursing CEU Application Form

This inservice is 3M Health Care Provider approved by the California Board of Registered Nurses, CEP 5770 for (1) contact hour. This form is valid up to five years from the date of publication.

1. Make a photocopy of this form.
2. Print your name, address and daytime phone number and position/title.
3. Add your social security number or your nursing license number.
4. Date the application and sign.
5. Answer the CE questions.
6. Submit this form and the answer sheet to:
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 Daytime phone () _____
 Position/Title _____
 Social Security or Nursing License Number _____
 Date application submitted _____
 Signature _____

Offer expires October 2010

Table 1
Saturated Steam Is Assured When the Temperature and Pressure Have the Following Relationship

Temperature (°F/°C)	Pressure PSIG (lbs/sq ingauge)	Pressure PSIA (sq in absolute)
249.7/121.0	15	29
251.6/122.0	16	30
253.4/123.0	17	31
255.2/124.0	18	32
257.0/125.0	19	33
258.7/126.0	20	34
260.4/126.9	21	35
262.0/127.8	22	36
263.6/128.7	23	37
265.2/129.6	24	38
266.7/130.4	25	39
268.2/131.2	26	40
269.7/132.1	27	41
271.2/132.0	28	42
272.6/133.7	29	43
273.9/134.4	30	44
275.3/135.2	31	45
276.6/135.9	32	46
278.0/136.7	33	47
279.3/137.4	34	48
280.5/138.1	35	49

ANSWERS

- | | |
|------|-------|
| 1. F | 6. T |
| 2. T | 7. F |
| 3. F | 8. T |
| 4. T | 9. T |
| 5. F | 10. T |

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Were the internal CI results read correctly?

- ▶ Did you use the correct internal CI for the cycle parameters?
- ▶ Do you store the internal CI according to manufacturer's instructions?
- ▶ Did you place the internal CI in the most challenging area of the package?
- ▶ Do all personnel know how to read internal CI results?

What was different about this load?

- ▶ Was the sterilization time, temperature and pressure correct for the load contents?
- ▶ Are you following the medical device manufacturer's instructions for use, which may include extended sterilization cycle and drying times?
- ▶ Did you do product testing to determine if you could effectively process all medical devices?
- ▶ What kind of items were in the load and how many packs were in the load?
- ▶ Was there enough room between packs for the sterilant to penetrate?
- ▶ Were the packs properly positioned to allow sterilant penetration?
- ▶ Are you correctly processing container systems?
- ▶ Did you do product testing to determine if you could effectively process the container system?
- ▶ Are the filters and valves correctly positioned and functioning?

What time of the day or what day of the week or month did the failure occur?

- ▶ What are the steam boiler demands at that time?
- ▶ When did they add boiler additives to the steam line?
- ▶ Have the type of boiler additives changed?
- ▶ What are the water pressure and temperature demands at the time?
- ▶ Is there any construction at the hospital that could effect the steam or water lines?

What time of the year is it and what is the weather like?

- ▶ Are steam pipes properly insulated?
- ▶ Are steam pipes located inside the building or is the steam obtained from a distant facility?
- ▶ Do boiler demands change with the season?
- ▶ Do water demands change with the season?

What else has changed with the steam supply?

- ▶ What is the water supply (public utility, private contractor, etc.)?
- ▶ Has that water supplier made any recent changes or modifications?
- ▶ Did you change the vendor of the chemicals used to treat the water?
If yes, when?
- ▶ Has the vendor changed chemicals or suppliers recently?
- ▶ When did you last blow out the steam lines?
- ▶ When did you last clean the traps?
- ▶ Have there been any changes to the water or steam distribution system?
- ▶ Have you solicited comments for the personnel operating the steam boilers?

correcting steam quantity and quality problems and water pressure and temperature. Periodically review the changes to ensure they are still in place to minimize the chances of another sterilization process failure from occurring for the same reason.

Placing the Steam Sterilizer Back Into Routine Use

After the reason for the failure has been determined and corrected, AAMI sterilizer efficacy testing should be performed. See the previous section “Sterilizer Efficacy Testing” on page 88 for more details.

When the sterilizer efficacy testing indicates acceptable results, i.e, the BD tests show an acceptable color change and the BIs are negative, the sterilizer can be placed back into routine use.

Summary

Sterilization process failures are the result of a series of unfortunate events whose cause needs to be identified and corrected so the sterilizer can be retested and placed back into routine use. To identify the reason for a steam sterilization

process failure, additional testing with BI test packs/PCDs may need to be done and questions need to be asked about the entire process. Next time a steam sterilization process failure occurs, put on your Sherlock Holmes hat, find your magnifying glass, and start looking for clues. If you need help, call us and we'll be your Dr. Watson. †

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