



**CONSOLIDATED  
STERILIZER SYSTEMS**

THE DEFINITIVE GUIDE TO

# Steam Sterilization Cycles



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# Modern steam autoclaves have the ability to sterilize nearly any type of load—everything from glassware to redbag waste to surgical packs.

Gravity, Liquids, and Vacuum Cycles are the most commonly utilized steam sterilization cycles as they can accommodate a wide variety of these autoclave load types. Some loads, however, (e.g. syringes, contact lenses, certain types of media, etc.) require special cycle configurations that employ pressure or temperature ramping, for instance. Fortunately, because of advanced autoclave control systems, today's steam autoclaves can be configured with specific parameters of varying times, temperatures, and pressures suitable for each load and application type.

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## This eBook was written for the following reasons:

### 1. Inform

To inform you of the different types of steam sterilization cycles available.

### 2. Help

To help you identify the proper steam sterilization cycle for each load type.

### 3. Explain

To explain how and when to use various steam sterilization cycles.

We hope you find this eBook informative and helpful. Thanks for reading.

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# Overview of The Sterilization Cycles Discussed in this eBook

Steam Sterilization Cycles	Description	Typical Application or Load Type
Gravity Cycle	The most basic sterilization cycle. Steam displaces air in the chamber by gravity (i.e. with out mechanical assistance) through a drain port.	Glassware, unwrapped goods, waste, utensils, redbags.
Vacuum Cycle	Air is mechanically removed from the chamber and load through a series of vacuum and pressure pulses. This allows the steam to penetrate porous areas of the load that couldn't otherwise be reached with simple gravity displacement.	Wrapped goods, packs, animal cage bedding, cages, porous materials, redbags.
Liquids Cycle	A gravity cycle with a slower exhaust rate to minimize boil-over.	Media, LB broth, water, etc.
Immediate-Use (Flash) Cycle	High temperature cycle (over 270° F) for a shorter period of time.	Unwrapped goods.
F <sub>0</sub> Cycle	Sterilization begins when temperature reaches a minimum of 212° F and is completed when the F <sub>0</sub> set-point is achieved. F <sub>0</sub> is adjustable.	Heat-sensitive media and liquids.
Air-Over-Pressure Cycle	Air maintains the pressure in chamber during exhaust phase until temperature of load drops below an adjustable value.	Small quantities of liquids (<10ml/vial) in danger of boiling over.
Steam-Air-Mix Cycle	Sterilization at an elevated pressure relative to temperature. Extra pressure is achieved using air.	Liquid-filled syringes.
Rapid Cool Cycles	During the cooling phase, cold water enters the jacket or chamber to speed up the cooling process.	Customers looking to decrease cycle time.
Low Temperature Cycle	Sterilization near the boiling point of water (180°-220° F).	Inspissation or pasteurization of heat-sensitive goods.
Product Lifecycle Testing	Sterilization conditions sharply accelerate product aging to evaluate the lifecycle of a product.	Textiles, medical goods, consumer goods.
Bowie-Dick Test Cycle	Daily air removal test, typically for healthcare applications.	Validating the sterilizer.
Vacuum Leak Test Cycle	Tests for air-tight integrity of chamber.	Validating the sterilizer.

# Steam Sterilization Basics

Sterilization is the practice of “destroying completely all forms of microbial life, including viruses” (Perkins 156). Steam autoclaves achieve sterilization by exposing loads to a combination of moisture and heat through direct contact with steam. Microbial death occurs because proteins and nucleic acids in the cell wall rapidly denature at high temperatures.

Steam sterilization occurs in three distinct phases: Purge, Sterilization, and Exhaust. During the Purge phase, steam enters the autoclave chamber (steam has a lower density than air and rises to the top of the chamber) and displaces or “pushes out” the existing ambient air. Complete air removal from the chamber is essential for achieving sterilization because air has an adverse effect upon steam penetration of porous loads. In addition, steam and air don’t mix well, which can result in variations in temperature within the chamber thus comprising the sterilization process (Perkins 114).

After all of the air is purged from the chamber, the temperature rises to the sterilization set-point and the Sterilization phase begins. The autoclave maintains this set temperature for a time adequate to eliminate all microbial life. Finally, the sterilization cycle enters the Exhaust phase where the chamber is exhausted of steam and returned to ambient temperature and pressure.

# Gravity Cycle



The traditional “Gravity Cycle” is the most common and simplest steam sterilization cycle.

During a Gravity Cycle, steam enters the autoclave chamber and, within a couple of minutes, displaces the air. As steam fills the chamber, the air is forced out through a drain vent. By pushing the air out, the steam is able to directly contact the load and begin to sterilize it. At the end of the Sterilization phase, the steam is exhausted and the chamber returns to ambient temperature and pressure.

At the end of a Gravity Cycle, the load can still be hot and possibly wet. To address this issue, gravity autoclaves can be equipped with a post-cycle vacuum feature to assist in drying the load. If equipped with this feature, the autoclave runs a normal Gravity Cycle through the end of the Sterilization phase, then a vacuum pulls steam and condensation through the drain vent during the Exhaust phase. The longer the vacuum system runs during the dry phase, the cooler and dryer the goods will be when removed from the chamber.

**Gravity Cycles are commonly used on the following loads:**

Glassware | Unwrapped Goods | Waste | Utensils | Redbags

# Vacuum Cycle



There are certain types of applications where air is not easily displaced from the chamber or load.

Gravity air displacement (as described earlier) is not as effective on porous loads or partially vented containers. For example, when sterilizing loads such as cages with animal bedding, wrapped goods, surgical packs, etc., it is best to use a Vacuum Cycle.

An autoclave configured to run a Vacuum Cycle will be equipped with a vacuum system. Most autoclaves have two options for vacuum systems: a water ejector (with optional booster pump) or a liquid ring vacuum pump.

A typical Vacuum Cycle will begin with a series of alternating steam pressure injections and vacuum draws (also called pulses) to dynamically remove the air from the chamber. Drawing a vacuum to remove ambient air from the chamber allows steam to be sucked into areas where it would otherwise have difficulty penetrating. The absence of air within the chamber allows “steam to penetrate the load almost instantaneously” resulting in more reliable sterilization and shorter sterilization cycle times (Perkins 124).

Once sterilization is complete, a post-cycle vacuum can be programmed to enhance and quicken the drying process.

## Vacuum Cycles are commonly used on the following loads:

Wrapped Goods | Packs | Animal Cage Bedding | Cages | Porous Materials | Redbags

# Liquids Cycle



From lysogeny broth to agar, almost every lab must sterilize some type of liquid solution during daily operations.

Liquids are not sterilized using a normal Gravity or Vacuum Cycle due to a phenomenon known as “boil-over” (see insert). The sterilization of a liquid in open or vented containers requires a special cycle known as the Liquids cycle.

“Boil-over” is simply a liquid boiling so violently that it spills over the top of its container. It occurs in standard Gravity and Vacuum cycles because the pressure in the autoclave chamber is released too quickly during the exhaust phase. Boil-over can result in significant volume loss and unwanted spills in the chamber that require subsequent cleanup.

To help prevent boil-over, the chamber pressure must be released slowly during the Exhaust phase. The Liquids Cycle is configured so that the chamber pressure is exhausted at a slower rate than standard Gravity or Vacuum cycles. Controlling the exhaust rate allows the liquid load to cool off as the surrounding chamber pressure is decreased. This process is controlled by the autoclave’s control system.

Be sure your autoclave is programmed and equipped with the right software and hardware to handle a slow exhaust Liquids Cycle. Quite often, a Jacket Blowdown option will be supplied to assist with minimizing boil-over. During a Liquids Cycle, this option automatically exhausts the steam from the jacket (which surrounds the chamber) and thus allows heat to be drawn out of the chamber and the liquid load at a faster rate.

**Liquids Cycles are commonly used on the following loads:**

Media | LB broth | Water



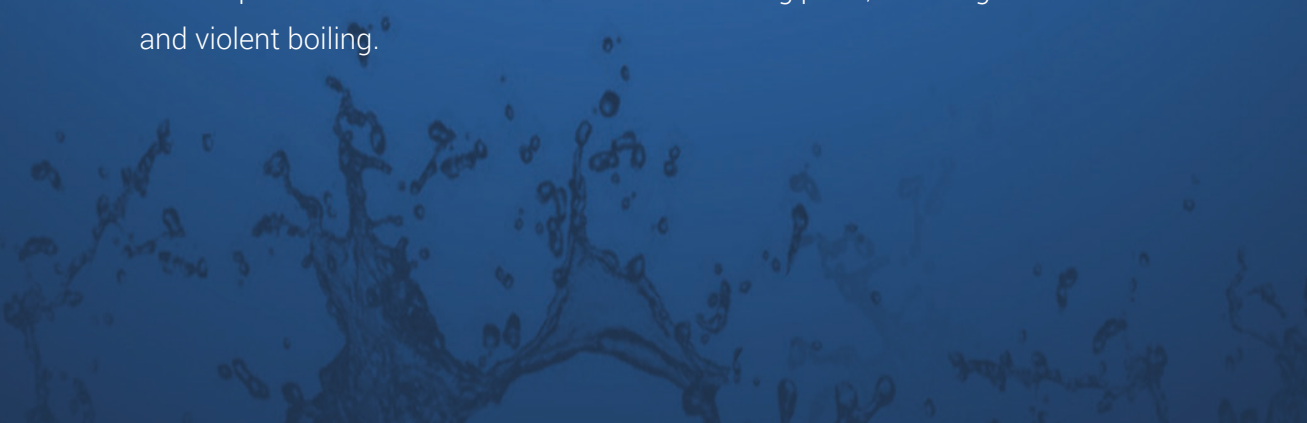
# WANT TO KNOW MORE?

## Learn about boil-over.

### **What causes a liquid to boil-over?**

Well, let's start by thinking about boiling a pot of water. At sea level, water boils at 212°F (100°C). In Denver, CO, however, where the elevation is 5,280 ft. above sea level, water boils at 203°F (95°C). Why is there a difference in boiling temperature? The answer is in the elevation, and the amount of atmospheric pressure pushing "down" on the water. At sea level, the atmospheric pressure is 14.6 psia (equivalent to 0 psig or 0 gauge pressure), while Denver's atmospheric pressure is only 12.1 psia. This relationship between pressure and temperature is what determines the boiling point of water; not just its temperature.

Now, let's think about the conditions inside an autoclave. During sterilization, a liquid load is heated to a temperature of 250°F (121°C). This temperature can only be achieved if the liquid load is subjected to steam pressure. During the Sterilization phase, an autoclave chamber typically operates at a pressure of 15 psia above atmospheric pressure (roughly 29.6 psia). This additional pressure is just enough to keep the liquid load from boiling. Upon completion of the Sterilization Cycle, the chamber must exhaust the steam, which means the temperature and pressure in the chamber will decrease. To prevent boil-over, the chamber pressure must decrease slowly to allow the temperature of the load to remain below the boiling point. If the pressure is exhausted all at once, the temperature of the load will be above its boiling point, resulting in instant and violent boiling.

A decorative graphic at the bottom of the page showing a splash of water with many small droplets, rendered in a dark blue color against the background.

# An Important Note About Liquids Cycle Times

It is important to recognize that larger liquid loads will take longer to both heat up and cool down. See the chart below:

Recommended Liquids Cycle Times

Temperature Setting	Liquid Quantity (mL)	Time Setting (minutes)
250°F (121°C)	75	25
250°F (121°C)	250	30
250°F (121°C)	500	40
250°F (121°C)	1000	45
250°F (121°C)	1500	50
250°F (121°C)	2000	55

The autoclave operator should keep this chart in mind while sterilizing large beakers or carboys.

For instance, a 40-minute Liquids Cycle for a 500mL flask may not be a sufficient amount of time to sterilize a 5 L flask. It is a best practice to A) validate your liquid loads with hermetically sealed biological indicators and B) minimize container volumes so that cycle times remain manageable.

Although the Liquids Cycle prevents boil-over, it still allows a small percentage of the liquid load to evaporate. This can be an issue when sterilizing very small liquid volumes and any amount of liquid-loss is considered unacceptable. For these types of loads please refer to the Air-Over Pressure Cycle and the Steam-Air-Mix Cycle.

# Why To Autoclave Liquids With a Load Probe

A load probe is a temperature sensing probe located inside the laboratory's autoclave chamber. It is configured such that the user can place the tip of the probe within the load being sterilized. Typically, it is placed in the coldest or most difficult to sterilize location. The coldest point in a liquids load is the center of the largest volume (i.e. in the center of a 2L flask). Similarly, the coldest point in a solid load is at the center of the densest bag or pack.

Laboratory autoclaves without a load probe measure temperature at the chamber drain (the coldest point in a chamber) and account for sterilization time when the chamber reaches 250°F. The ambient chamber temperature, however, can often be higher than the temperature at the center of the load—a phenomenon referred to as “load lag”<sup>1</sup>. This occurs because as steam condenses on a load, the heat must be conducted from the surface to the center of the load. While this is occurring, the load temperature “lags” behind the chamber temperature. If unaccounted for, a discrepancy between the chamber temperature and internal load temperature heightens the risk of non-sterilization.

When running a sterilization cycle with a load probe, the autoclave uses the load probe temperature reading as the primary control for the cycle. Therefore, if the cycle parameters are set for 30 minutes at 250°F, the sterilizer doesn't start the 30 minute timer until the load probe senses a temperature of 250°F. The reason behind delaying the timer is a phenomenon referred to as load lag.

In order to guarantee sterilization is achieved, the load must reach at least 250°F (121°C) for a specified amount of time. For example, most LB broth must be sterilized for 15 minutes at 250°F. For loads that exhibit a large load lag (i.e., dense, solid loads or containers with greater than 500 ml of liquid), a load probe should be used to measure the temperature within the load itself.

Using a load probe ensures the load has been subjected to a temperature adequate for sterilization for the required amount of time.

# Immediate-Use (Flash) Cycle



**Note:** The Immediate-Use or “Flash” Cycle is not typically performed in laboratory autoclaves, but is quite common in healthcare autoclaves.

Immediate-Use Cycles are shorter than the typical Gravity or Vacuum cycles that are performed at 250°F (121°C). The cycle time for an Immediate-Use Cycle is typically 3-10 minutes in length. In order to achieve sterilization in this “short” amount of time, an Immediate-Use Cycle is performed at the elevated temperature of 270-275° F (132-135° C). Unwrapped goods will sterilize on the shorter end of that time frame (3-5 minutes) while wrapped goods run for 6-10 minutes, depending on the make and manufacturer of the autoclave as well as the device. All Immediate-Use Cycles are conducted as gravity cycles (i.e. without pre-vacuum pulses).

There has been much debate around the antiquated term “flash sterilization.” A concerted effort has been made by the Association for Advancement of Medical Instrumentation (AAMI), the Joint Commission (JC) and the Food and Drug Administration (FDA), to clarify the use of flash sterilization, which these organizations now refer to as “immediate use” sterilization. This sterilization cycle is not intended for routine instrument sterilization but only when specific instruments are needed for an emergency procedure.

Some dental practices use this sterilization cycle for processing all of their instruments because of the shorter sterilization cycle or because the practice may not have a large inventory of handpieces (i.e. the faster turnaround greatly improves operating efficiency). These reasons, however, do not justify what has become the misuse of the Flash Cycle. Performing correct, albeit longer, sterilization cycles (see gravity and pre-vac cycles) is the prudent choice.

## Flash Cycles are commonly used on the following loads:

Unwrapped Goods

## Immediate-Use Cycles are typically found on smaller autoclaves with chamber volumes of less than 300L, ideal for the operating room or a dental practice.

Examples of standards and practices for Immediate-Use sterilization can be found with the Association for the Advancement of Medical Instrumentation (AAMI), the Association of periOperative Registered Nurses (AORN), and the Centers for Disease Control and Prevention-Healthcare Infection Control Practices Advisory Committee (CDC-HICPAC).

All personnel operating the autoclave should be educated regarding the different types of steam sterilizers (i.e., gravity versus vacuum) and the different types of steam sterilization cycles.

### Immediate-Use sterilization should NOT be performed on the following devices:

- Implants
- Post-procedure decontamination of instruments used on patients who may have Creutzfeldt–Jakob disease (CJD) or similar disorders
- Devices or loads that have not been validated with the Immediate-Use Cycle
- Devices that are sold sterile and intended for single-use only



# F<sub>0</sub> Cycle



The F<sub>0</sub> Cycle (pronounced f-sub-zero or f-sub-oh) is especially useful for sterilizing large liquid volumes with, say, greater than 2 Liters of fluid. This cycle is useful if you are concerned about caramelized broth or long sterilization times (over 90 minutes).

The term “F<sub>0</sub>” is defined as the number of equivalent minutes of steam sterilization at 250°F (121°C) delivered to a load (product). For example, if a cycle has an F<sub>0</sub> value of 12, the sterilization effectiveness of that cycle is equal to 12 minutes at 250°F (121°C) regardless of the process temperature and time used in the cycle.

The basic concept behind F<sub>0</sub> is that some microbes are destroyed at temperatures below the sterilization set point (e.g. 250°F) and, thereby, before the Sterilization phase has initiated. This is good news if you have broth that is sensitive to caramelization or prolonged exposure to heat. The F<sub>0</sub> Cycle is designed to give you “credit” for the sterilization that happens while your load is rising to the temperature set-point, thus reducing the overall cycle time.

Note: The theory and equations behind the F<sub>0</sub> Cycle go beyond the scope of this eBook.

More information can be found here:

<http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/validation/mhsp-schpp-eng.php#a10>

## F<sub>0</sub> Cycles are commonly used on the following loads:

Heat-Sensitive Media | Liquids

## Before we explain the FO concept further, let's review the process steps of a basic Liquids Cycle that is controlled by a Load Probe.

1. Press the Cycle "Start" button. A cycle is initiated.
2. Steam is injected into the chamber until the chamber temperature reaches the sterilization set-point (usually 250°F or 121°C).
3. The chamber temperature is maintained at slightly above the sterilization set-point until the load temperature reaches the sterilization set-point. This portion of the cycle is referred to as the "lag time" because the load temperature is "lagging behind" the chamber temperature. See fig. 1.
4. Once the load temperature has reached the sterilization set-point, only then can the sterilization timer start.
5. When the timer completes, the chamber is exhausted slowly to prevent boil-over and the cycle ends.



Figure 1: Sterilization without a Load Probe

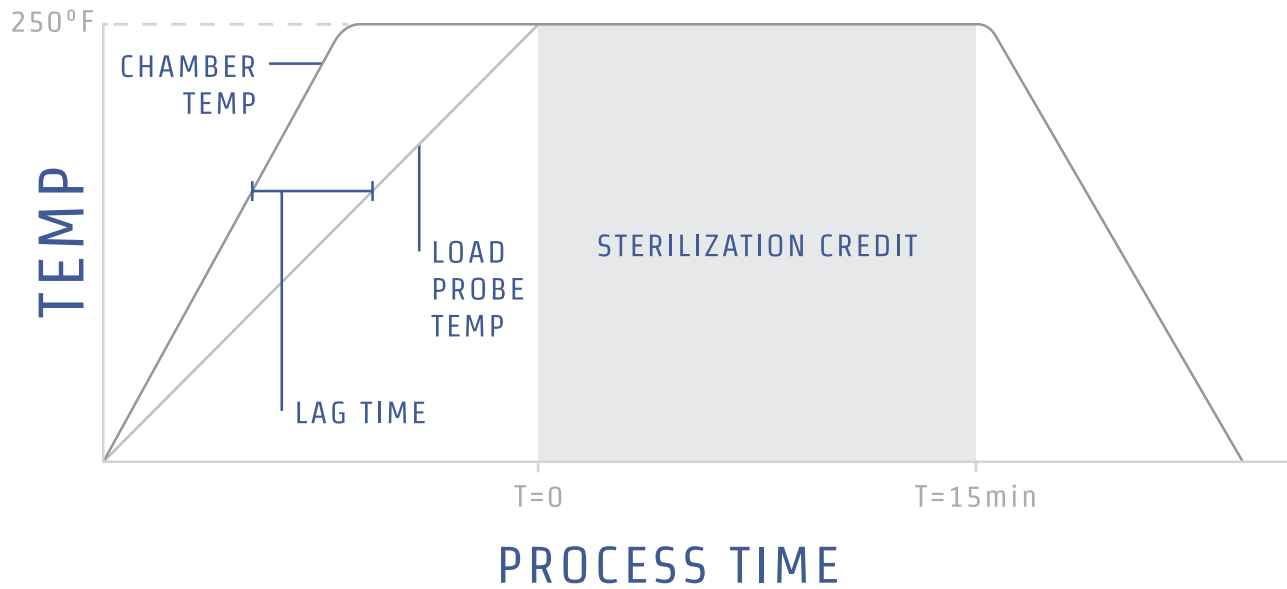


Figure 1 shows a typical time-versus-temperature profile for sterilizing a liquid load without using  $F_0$ . Notice the significant lag time and how sterilization credit is only applied after the load probe reaches 250°F. Depending on the load volume, it can take the load 30-90 minutes to reach sterilization temperature. Extended lag time creates longer-than-necessary cycles that can cause problems for busy labs (eg. caramelized broth, long wait periods, etc.).

Figure 2: Sterilization with a Load Probe

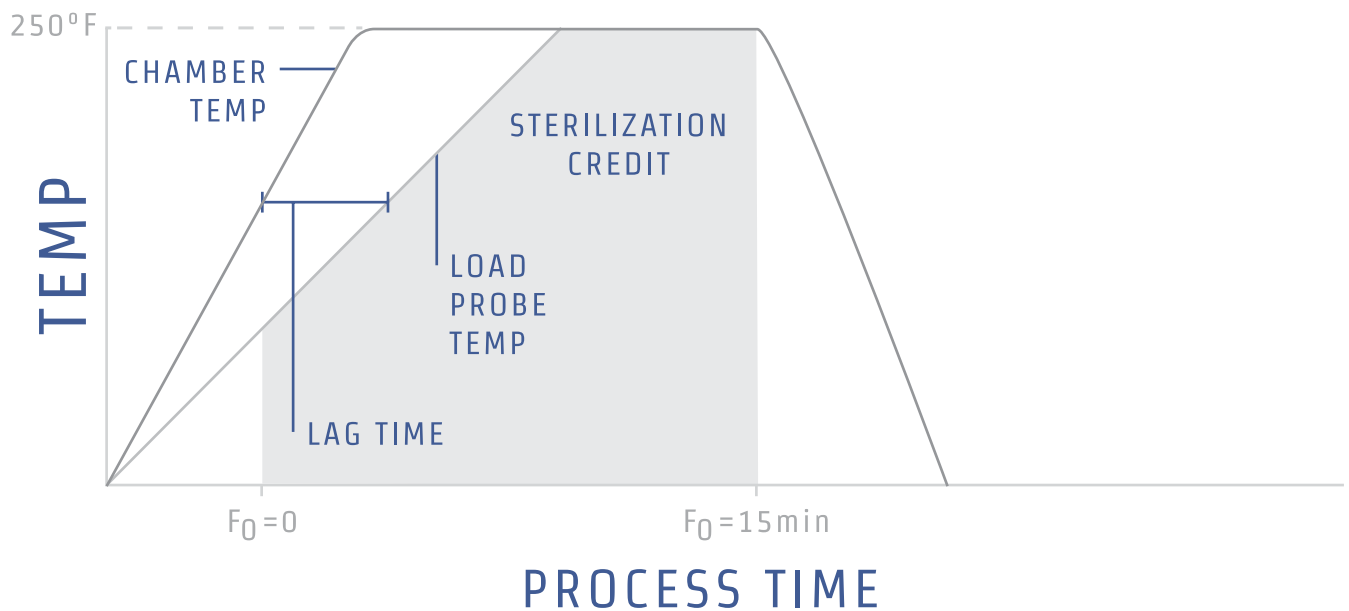


Figure 2 shows the same time-versus-temperature profile for sterilizing liquids using  $F_0$  Cycle. Sterilization credit is issued as the load comes up to temperature, reducing the overall cycle time.



# Let's look at an example of an $F_0$ cycle.

If the load is at 232°F for 15 minutes, this creates the sterilization equivalent of being at 250°F for 1.5 minutes.

This is known as the  $F_0$  value. The  $F_0$  value tells us the equivalent amount of sterilization (in minutes) that would have been completed had the load been at 250°F. (As temperature increases, so does sterilization/kill rate.)

By calculating the  $F_0$  values every few seconds over the length of a cycle and adding them up, a total  $F_0$  value for the cycle is determined. Once the desired  $F_0$  value is reached, the cycle will have achieved sterilization, regardless of whether the load ever reached the original set sterilization temperature. Therefore, the  $F_0$  cycle becomes extremely useful for autoclaving large volumes of liquid in a timely manner, as quite a bit of "sterilization credit" is accumulated during the lag time for these larger loads.

**Before enlisting the  $F_0$  Cycle at any facility, be sure you fully understand when and how to use this advanced cycle.** Done correctly, this cycle could help improve overall efficiencies and lead to more accurate sterilization processes.



# Air-Over-Pressure Cycle



As discussed earlier, a Liquids Cycle prevents boil-over; however, the load may still experience up to 5% volume loss due to evaporation.

An Air-Over-Pressure Cycle is a variation of the Liquids Cycle used for loads that are extremely sensitive to evaporation. Typical applications for this cycle include pre-filled pipet tips, small pre-filled vials, loosely capped flasks, foil sealed glassware, or any partially vented containers where even small amounts of evaporation are not acceptable.

Boil-over is circumvented in a Liquids Cycle by slowly releasing chamber pressure during the Exhaust Phase. The Air-Over-Pressure Cycle takes this concept a step further by increasing chamber pressure during the Exhaust Phase. As steam is exhausted, cool compressed air is simultaneously introduced so that surrounding pressure on the liquid is maintained while temperature drops.

For example, if the sterilization pressure is 15-18 psi, a typical Air-Over-Pressure cycle will pressurize the chamber to 30 psi, allowing the load to cool down while under pressure. The temperature of the load is continuously monitored by a Load Probe throughout the cooling phase.

Once the load temperature falls to a set-point, typically 200°F-210°F, the risk of evaporative boiling loss has been mitigated and sterilization has been achieved.

Functionally, an Air-Over-Pressure Cycle is similar to a Steam-Air-Mix Cycle (see next page) in that both cycles pressurize the autoclave chamber using a combination of steam and compressed air. A Steam-Air-Mix Cycle, however, uses air during both the Sterilization and Exhaust phases whereas an Air-Over-Pressure Cycle uses air only during the exhaust phase. A Steam-Air-Mix Cycle is primarily used for applications where sealed containers may develop internal pressure and rupture during the Sterilization Phase. An Air-Over-Pressure Cycle is primarily used to minimize loss from evaporation during the Exhaust Phase. It is important to note that in the sterilization industry the Steam-Air-Mix and Air-Over-Pressure cycles can be collectively referred to as just Air-Over-Pressure.

**Air-Over-Pressure Cycles are commonly used on the following loads:**

Small quantities of liquids (<10ml/vial) in danger of boiling over

# Steam-Air-Mix Cycle



The Liquids and Air-Over-Pressure Cycles described earlier are only applicable for open or partially vented containers. Sterilizing hermetically sealed containers requires a special cycle known as the Steam-Air-Mix.

Consider a liquid-filled syringe as an example. When the syringe heats up, the liquid inside expands and exerts pressure on the stopper. If the stopper is not able to resist the internal liquid pressure, it will be forced off. Then, not only is the syringe unusable, it will have made a mess of the rest of the load and inside the chamber.

The obvious solution is to increase the autoclave chamber pressure in order to balance out the internal and external pressure of the syringe (or other sealed container). If the pressures are equal, the stopper should not move. But how is this accomplished? One way to increase external pressure is to simply inject more steam in to the chamber. Unfortunately, when steam pressure rises, temperature also rises, in turn causing the syringe's internal pressure to also rise. A Steam-Air-Mix Cycle solves this problem by injecting compressed air into the chamber during the Sterilization phase. Steam is injected in the chamber as needed in order to maintain the cycle's temperature setting.

After the Sterilization phase is complete, it is necessary to maintain an elevated chamber pressure during the Exhaust phase in order to keep the syringe intact. However, as the temperature in the chamber falls, the internal pressure of the syringe will begin to fall as well, potentially causing the reverse-effect where the external (chamber) pressure compromises the syringe. To solve this, the chamber pressure is slowly reduced as the temperature falls.

The Steam-Air-Mix Cycle option requires a compressed air supply, and it is recommended for applications where a liquid is being sterilized in a sealed container that may be affected by pressure imbalances.

## Steam-Air-Mix Cycles are commonly used on the following loads:

Liquid-Filled Syringes

# Rapid Cool Cycles



Rapid Cool Cycles are utilized to quickly and effectively cool the load in the chamber.

By the end of a gravity or vacuum sterilization cycle, the load temperature is still very hot, above 200° F (93.3° C). As such, the autoclave operator must wear heat resistant gloves and other Personal Protection Equipment (PPE) in order to remove the load safely. Once hot items are removed, the operator must wait for these items to cool down on the bench before they can be used. This wait time can be problematic.

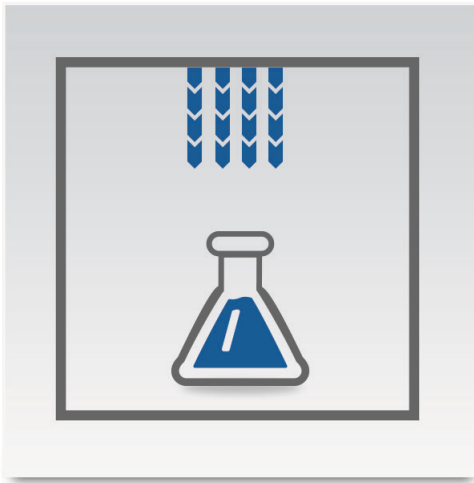
## Rapid Cool Cycles can provide three benefits:

- Safer handling of the load.
- Decreased wait-time between when the items (e.g. utensils, liquids, glassware, etc.) are removed from the autoclave and when they are safe to use for research experiments.
- Rapid product life-cycle testing. In this scenario, commonly used in medical device (e.g. implants) material compatibility studies, the temperature of the load is required to continually cycle between sterilization (i.e. 250°F) and room temperature (say, 75°F) for extended periods of time as defined by the validation protocol. Accelerating this cooling process can greatly shorten the total amount of validation time required to complete these studies—thereby increasing overall facility efficiencies.

## Rapid Cool Cycles are commonly used on the following loads:

Customers looking to decrease cycle time

# There are two types of Rapid Cool Cycles available: Spray and Jacket.



## Rapid Spray-Cool Cycle

The Rapid Spray-Cool Cycle directly cools the load by spraying cold water on the items within the chamber at the end of the Sterilization Cycle. Rapid Spray-Cool is most applicable for customers with non-porous products or items that do not need to be dry when removed from the autoclave. The cold water reduces the radiant heating effect on the product and cools it through convection. The appropriate quality of water should be used to maintain the integrity and sterility of the product.



## Rapid Jacket-Cool Cycle

Unlike the Rapid Spray-Cool Cycle, this cycle does not directly cool the load with water. Instead, cold water circulates around the jacket of the autoclave to reduce radiant heat and cool the load faster. Since the cold water remains in the jacket and never in contact with the load, it does not need to be sterile. This cycle is ideal for loads that cannot be wet when removed from the chamber or for items such as open glassware containers.

# Low Temperature Cycle



By default, most laboratory steam autoclaves operate in the range of 250–275° F (121–134°C).

However, some units can be configured to run cycles as low as 140°F to accommodate objects that are heat-sensitive and heat-coagulable. Units with the capacity to operate at lower temperatures are commonly and aptly referred to as Low Temperature or Isothermal autoclaves, and they can run the following cycles:

**Low-Temperature**

**Moist-Heat**

**Inspissation**

**Pasteurization**

**Fractional Sterilization**

The most common of these cycles is the Low Temperature Cycle, which operates at temperatures between 158–212°F (70–100°C) with no chamber pressure. The basic premise of these Low Temperature units is that steam flows freely and evenly throughout the chamber at atmospheric pressure. A basic laboratory autoclave that is not equipped as a Low Temperature unit will not evenly disperse the steam at a low temperature (temperatures below 212°F).

## Low Temperature Cycles are commonly used on the following loads:

Inspissation of pasteurization of heat-sensitive goods

# For those with a steam autoclave capable of running the Low Temperature Cycle, here are answers to two of the most commonly asked questions about the Low Temperature Cycle:

## When is it appropriate to use a Low Temperature Cycle?

An autoclave operator may need to sterilize objects that are not heat-stable, prone to congeal, or shouldn't reach temperatures higher than atmospheric steam. Examples include:

- Thermoplastics, like LDPE
- Sensitive liquids, like milk or baby formula
- Some medical devices
- Media and agar preparation, as this cycle allows for the media (agar) to melt without overheating it

Additionally, Low Temperature autoclaves can be used as a way to reduce (not eliminate) the total microbial burden of a given load.

## How long does a Low Temperature Cycle take?

Because these cycles operate at below the boiling point of water, cycle times should be longer than your typical steam sterilization cycle (at 250°F for 30 minutes). Typical Low Temperature Cycle times range from 45 to 90 minutes and will often be repeated for multiple days on the same load as not to denature or caramelize it.

As such, Low Temperature Cycles should be planned out thoughtfully and carefully, and, if applicable, be validated with biological indicators. In general, cycle times will vary depending on the size of your autoclave, the size and type of load, the temperature at which the autoclave is operating at, and how the load is packaged.

# Product Lifecycle Testing



Repeated exposure to an autoclave chamber's extreme temperature and pressure conditions allows Quality Control Specialists to sharply accelerate product aging and evaluate the lifecycle of a product.

Typically, this process requires that an individual (e.g. technician, scientist, engineer, etc) spend countless hours in front of an autoclave. What if you could program the autoclave to run multiple sterilization cycles (over multiple hours or days) with the press of a single button?

The purpose of performing a lifecycle test isn't necessarily to kill microbes. Instead, this testing is useful for simulating how products age over time when exposed to sterilization conditions (e.g. high temperature and pressure). Moisture, heat and pressure are factors known to accelerate the degradation of materials like plastics, polymers, natural fibers and some metals. Running multiple back-to-back cycles is especially useful, and often times required, to validate the integrity of items constructed of these materials. Furthermore, certain chemical reactions occur at quicker rates – according to Arrhenius' equation every 10°C increase in temperature doubles the rate of a chemical reaction. This accelerated testing can compress a year's worth of testing down to just weeks or even days.

Most autoclaves on the market are not equipped to run repeated, back-to-back cycles, without having the user present to initiate each cycle. To run a standard Gravity, Vacuum or Liquids Cycle, the operator initiates the process by selecting the Cycle Type, entering the appropriate sterilization parameters and pressing the start button. At the end of the cycle, the operator must open the autoclave door and remove the load before another cycle can be initiated. Product lifecycle testing in the above fashion is very time consuming, as it takes up valuable time to monitor the autoclave and restart every cycle.

**Product Lifecycle Testing Cycles are commonly used on the following loads:**

Textiles | Medical Goods | Consumer Goods



# What if this process could be automated?

This option exists on modern controllers and is quite useful.

The operator will simply select the Cycle Type (e.g. gravity cycle, 250°F, 45min) and activate the “Repeat Cycle” feature by inputting the desired Number of Repetitions, End-of-Cycle Temperature, and Wait-Time between Cycles. One could theoretically enter 1,000 repetitions thereby simulating years worth of cycles in days. Some autoclaves can also be configured to simulate the effects of thermal cycling and thermal shock by incorporating a Rapid Cool Cycle.

## Industries that Perform Product Lifecycle Testing

- Textiles: Medical cotton based fabrics sterilized at 270°F retained greater strength after 100 cycles than the same items sterilized at 250°F for a longer cycle time.
- O-Rings & Gaskets: Items used in high temperature sealing applications.
- Consumer Goods: Products to be used or stored in high heat and/or humidity environments like deserts or rain forest. Products that may be stored in buildings or locations with uncontrolled ambient conditions.
- Closed Cell Foam Insulation: Accelerated aging in an autoclave testing shows a decrease in tensile strength with prolonged exposure to heat and humidity.
- Medical: Designers of reusable medical instruments can test instrument resilience to steam sterilization. This helps determine the number of times an instrument can be re-used before disposal is necessary. Prosthetics and other medical devices also undergo accelerated aging tests to ensure they perform properly over time.

In short, an autoclave configured for continuous product lifecycle testing can reduce costs by saving time and resources.

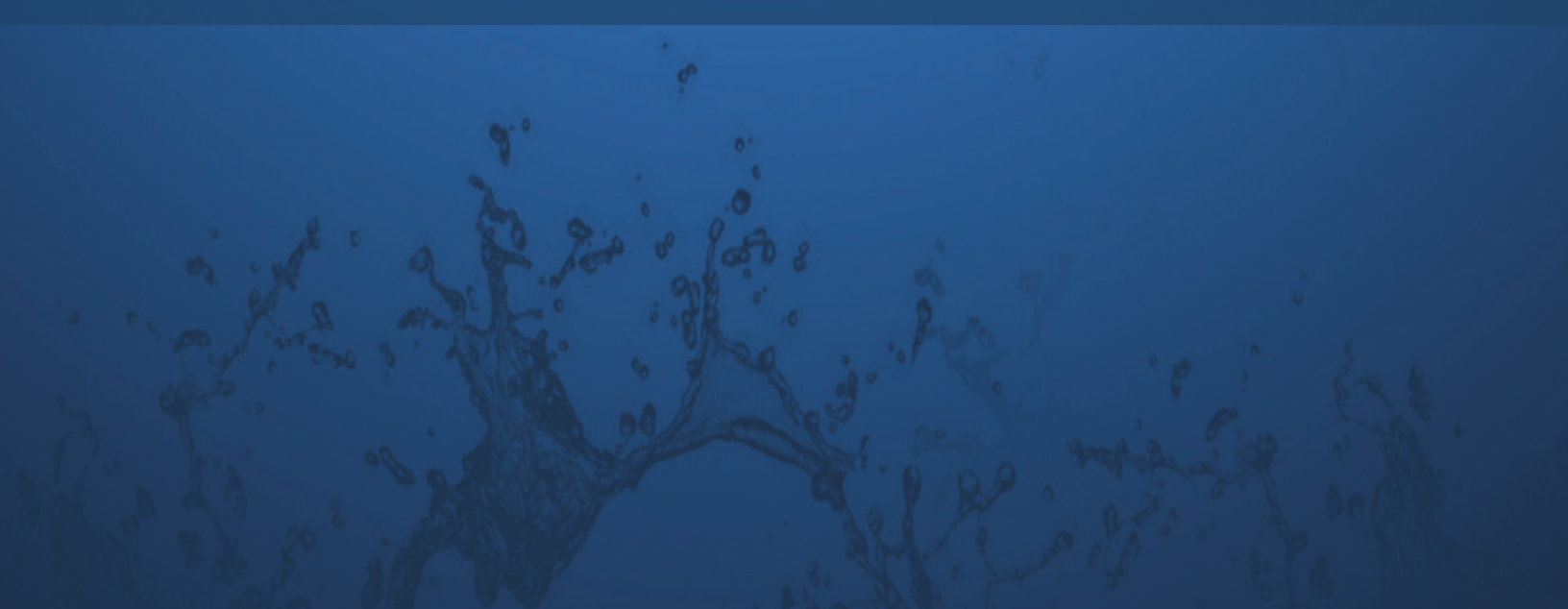
# Test Cycles

It is important to ensure that materials processed in a laboratory autoclave have been exposed to adequate conditions for sterilization.

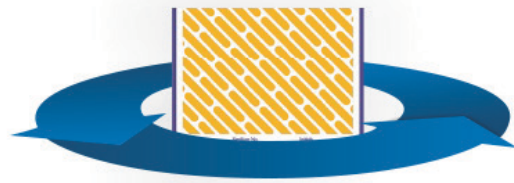
**Sterilization validation can be accomplished in a number of ways:**

- Physical monitoring through the autoclave's display screen or print-out
- Chemical monitoring with chemical indicators
- Efficacy testing with biological indicators
- Operational testing of the autoclave
  - Bowie-Dick Test
  - Vacuum Leak Test

The following validation tests are used in a variety of applications, including the sterilization of medical devices, pharmaceutical goods, and waste from bio-containment laboratories.



# Bowie-Dick Test Cycle

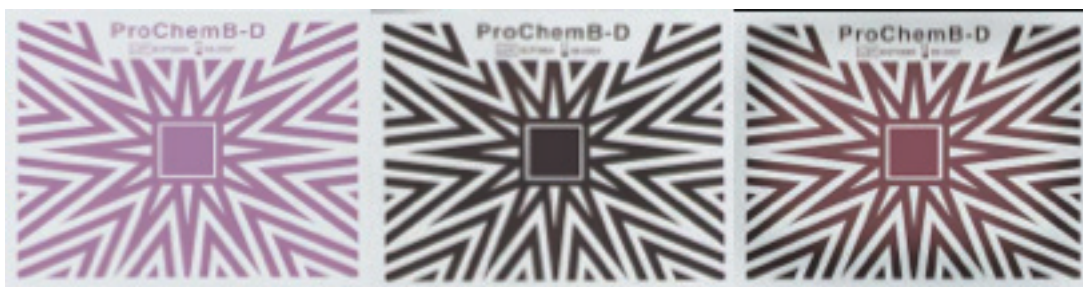
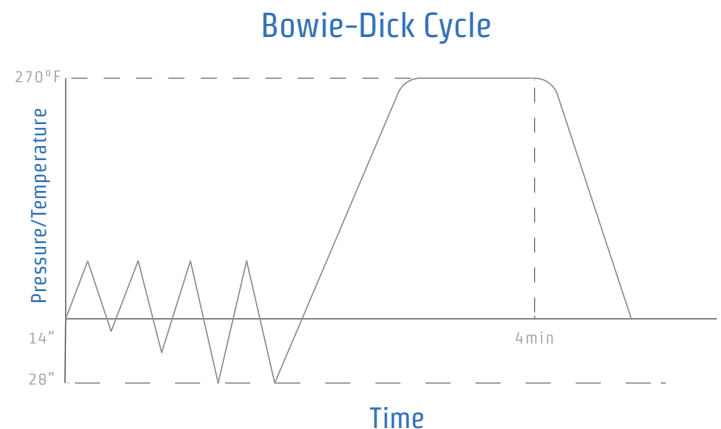


While it's not a substitute for sterility assurance testing, the Bowie-Dick Test demonstrates proper air removal from the chamber of a pre-vacuum autoclave.

Pockets of cool air act as a barrier that prevents steam from penetrating porous loads, therefore, the air must be removed by vacuum.

The first Bowie-Dick test packs consisted of 29-36 huckaback towels, each folded and stacked to a height of 10 -11 inches, with autoclave tape in the middle of the pack. Today, laboratories use small disposable packs made of thermochromatic (temperature sensitive) paper sandwiched between porous substrates and reticulated foam. To run the test, a pack is placed in an empty chamber on the lowest shelf above the drain (the coldest point in the chamber) and a "Bowie-Dick Cycle" is initiated. The sterilization cycle consists of three to four pre-vacuum pulses before reaching the set point of 270 °F.

The thermochromatic paper inside the pack will indicate if steam has penetrated the porous load. A Bowie-Dick Test pack that shows a uniform dark black color pattern indicates a successful vacuum and full steam penetration, whereas no or partial color change indicates an unsuccessful test cycle.



Unexposed

Pass

Fail

This test can be performed daily, or less frequently depending on the facility's needs and SOP. If the Bowie-Dick Test should fail, both the autoclave and the laboratory facility utilities should be checked. Any Prevac Cycle should not be used with any confidence until the test is repeated with a passing result.

# Vacuum Leak Test Cycle



The Vacuum Leak Test is used to determine the air-tight integrity of a pre-vacuum autoclave's chamber and plumbing system.

This test exposes the autoclave's plumbing and components to vacuum conditions and measures how much vacuum depth was lost over a given period of time. A typical Vacuum Leak Test Cycle will consist of three vacuum/pressure pulses followed by a 15 minute dwell period at deep vacuum. Upon completion of the cycle, a leak rate will be displayed on the autoclave's control screen in units such as psia/min, kPa/min, mbar/min, or mmHG/min. The pass/fail criteria for a Vacuum Leak Test is ultimately determined by the specifications of the user, but **industry standards call for an average leak rate of 1mmHG/min or less**. The frequency of the test depends on the facility SOP and risk tolerance. Regularly performing a Vacuum Leak Test allows greater confidence in the integrity of the chamber and plumbing.

Laboratory autoclaves are calibrated upon installation, but it is important to periodically validate that they are operating properly. The Bowie-Dick Test and Vacuum Leak Test are simple operational checks that should be incorporated into the Standard Operating Procedures wherever prevacuum autoclaves are used.

## Test Cycles are commonly used on the following loads:

Validating the sterilizer

# Have more cycle questions?

Do you have additional questions about sterilization cycles? Are you curious about how to program custom cycles?

Contact the engineering team at Consolidated Sterilizer Systems with your questions by filling out the form found here:

<http://www.consteril.com/resources/sterilization-cycles/>

# Resources

## **Association for the Advancement of Medical Instrumentation.**

ANSI/AAMI ST79: 2010 & A1:2010—Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. Arlington, VA: Association for the Advancement of Medical Instrumentation, 2010.

## **Association for the Advancement of Medical Instrumentation.**

ANSI/AAMI ST40—Table-top Dry Heat (Heated Air) Sterilization and Sterility Assurance in Health Care Facilities. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2004.

## **Association for the Advancement of Medical Instrumentation.**

ANSI/AAMI ST-8

## **Centers for Disease Control.**

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008.

## **Principles and Methods of Sterilization in Health Sciences.**

By John J. Perkins, Charles C Thomas Pub Ltd; 2 edition 1973

## **Recommended practices for cleaning and care of surgical instruments and powered equipment.**

In: Standards, Recommended Practices and Guidelines. Denver, CO: AORN, Inc; 2010.

## **Recommended practices for sterilization in the perioperative setting.**

In: Standards, Recommended Practices, and Guidelines. Denver, CO: AORN, Inc; 2010.

## **“The Effect on Cotton of Steam Sterilization with Pre-Vacuum.”**

Henry, P.S.H., Journal of Applied Bacteriology, Volume 27.

## **“Towards Ageing Protocols for Service in Hostile Conditions.”**

Broughton, William R. National Physical Laboratory, Teddington, Middlesex, UK



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