

HOW TO: Guide to Steam Sterilization Cycles – Steam Flush Pressure Pulse

Introduction

There are three types of steam sterilization cycles recognized by the Association for the Advancement of Medical Instrumentation (AAMI). They are gravity, prevacuum and steam flush pressure pulse (SFPP). These cycles differ in the way air is removed from the load during conditioning and may have different exposure times depending on the type of load being processed. Both Prevacuum and SFPP are classified as Dynamic Air Removal cycles by AAMI. Figure 1 illustrates the typical profile for each type of cycle. All validated steam sterilization cycles provide efficacious sterilization when used according to manufacturer instructions, but dynamic air removal cycles are preferred because they are more efficient at removing air from the load.

Anatomy of a Steam Sterilization Cycle

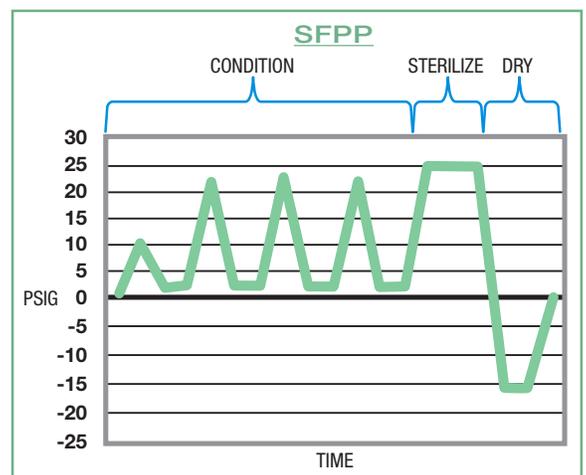
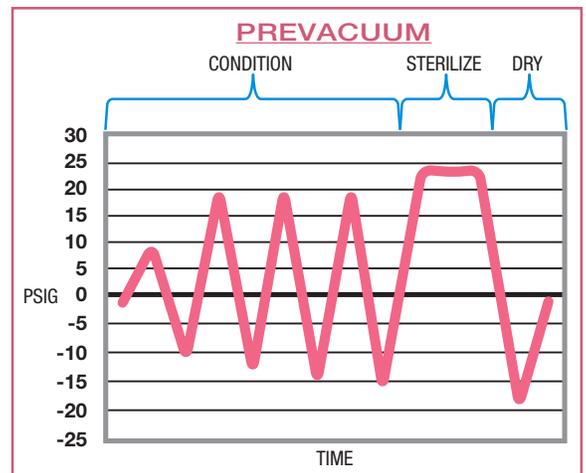
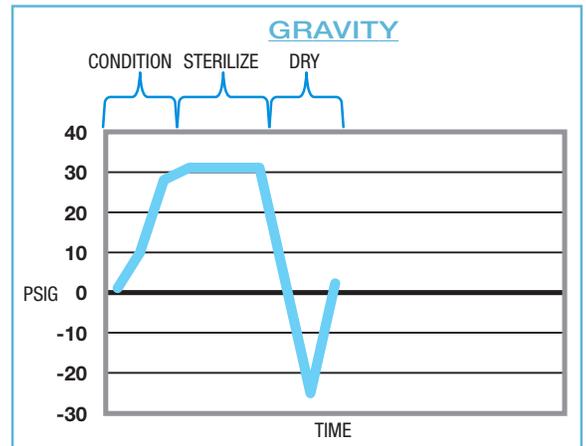
Steam sterilization cycles can be divided into three distinct phases; conditioning, exposure and drying. During conditioning, air is removed from the load and the items in the load are heated to the desired temperature for sterilization. Conditioning is important because if there is any air in the load it may prevent the sterilant from coming into contact with load items, leading to sterilization failure. During exposure, the load is held at a specific temperature for a time known to provide effective sterilization. After exposure, steam is removed from the chamber and the load is dried to prevent recontamination of the instruments through wicking of microorganisms through a wet wrap.

During **gravity** cycle conditioning, steam displaces the air in the chamber and the force of gravity causes the heavier air to exit the chamber via the sterilizer drain. Gravity cycles typically require more exposure time because the air removal method is more passive in nature.

Prevacuum cycles condition wrapped loads through a series of pressurizations with steam and evacuations of the chamber using a mechanical vacuum system. The vacuum system facilitates more efficient air removal when compared to the gravity method, especially when processing lumened items. During evacuations of the chamber, the pressure in the chamber drops to below atmospheric. Consequently, if there are any leaks in the piping or sterilizer seal the potential exists to re-introduce air into the chamber.

The Bowie-Dick test is conducted daily to ensure that the vacuum system is adequately removing air from the chamber and should be used in conjunction with a weekly leak test to determine if there are leaks in the sterilizer plumbing or seal.

FIGURE 1.
TYPICAL STEAM STERILIZATION CYCLE PROFILES. PRESSURE VS. TIME
Note: Zero represents ambient atmospheric pressure.



The **SFPP** cycle was initially developed in 1988 and has been used for terminal steam sterilization since 1990 when it was cleared by the FDA for use in healthcare applications. The SFPP cycle conditions the load through a series of carefully controlled pressurizations and flushes with steam. No vacuum is drawn during conditioning and chamber pressures do not drop below atmospheric. Therefore, there is no need to conduct a daily Bowie-Dick test. Since the pressure in the chamber is greater than the ambient air pressure, reintroduction of air into the chamber through plumbing or seal leaks is eliminated, reducing the possibility of load recontamination.

● Dynamic Air Removal – The Common Denominator in Prevacuum and SFPP Cycles

The SFPP cycle has been cleared for use with AMSCO steam sterilizers since 1998. AAMI recognizes both the Prevacuum and SFPP cycle as a “dynamic-air-removal type”. Both AAMI ST8:2013 (Section 3.10) and AAMIST79:2010 (Section 2.25) define dynamic air removal cycles as “One of two types of sterilization cycles in which air is removed from the chamber and the load by a means of a series of pressure and vacuum excursions (prevacuum cycle) or by means of a series of steam flushes and pressure pulses above atmospheric pressure (steam-flush pressure –pulse [SFPP] cycle).” Both conditioning methods provide effective air removal from the load.

Following load conditioning, the sterilization phase of SFPP and Prevac cycles is the same, with exposure times of 4 and 3 minutes for temperatures of 270F° (132°C) and 275°F (135°C) respectively. After sterilization, both cycles use a vacuum to remove steam from the load and dry it. Both cycles have been validated by STERIS per AAMI ST8 to provide efficacious sterilization.

● Instrument IFUs and the SFPP Cycle

The FDA requires instrument manufacturers to identify at least one method of sterilization in their instructions for use. FDA and AAMI also recommend the use of industry-standard cycles for sterile processing wherever possible. Both Prevacuum and SFPP are recognized by AAMI as standard dynamic air removal cycles. However, many instrument manufacturers recommend processing with a standard prevacuum cycle in their instructions for use and end users may be uncertain if the SFPP cycle can be substituted

STERIS University Key Learning Objective → Since both prevacuum and SFPP cycles are considered of the dynamic air removal type, if an instrument manufacturer’s instructions for use state that a prevacuum cycle with sterilize time of 4 minutes 270F° (132°C) or 3 minutes 275°F (135°C) should be used for processing, the SFPP cycle with a sterilize time of 4 or 3 minutes, respectively, may be substituted.

● Benefits of SFPP

The SFPP cycle offers many benefits, including time and cost savings. Since there is no vacuum drawn during conditioning there is no requirement to run a Bowie-Dick test if only SFPP cycles are employed. Because SFPP conditions loads above atmospheric pressure, air cannot be reintroduced into the chamber through leaks in the sterilizer plumbing. This eliminates sterilizer downtime associated with leaks and saves the time and cost of reprocessing if a positive Bowie-Dick has been obtained while using Prevacuum cycles.

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