

# Sterilization Answer Man

## *Dynamic Air Removal Cycles*

Have you ever stood in front of your Vacuum Steam Sterilizer and watched the temperature and pressure gauges for the whole cycle? Watching grass grow might be more exciting. However, there are lots to learn by watching just how your cycle progresses through the entire cycle.

There are 6 distinctive phases to a dynamic air removal cycle. They are:

1. Preconditioning
  - a. Steam purge for a timed duration
  - b. Pressure pulses
2. Heat Up to the Exposure temperature
3. Exposure (time at temperature)
4. Exhaust to atmosphere
5. Drying under vacuum
6. Cycle complete

### *Preconditioning*

The preconditioning phase is critical for removing air from the chamber and from the load. We all know that the presence of air inhibits steam contact and unless the items come in contact with moist steam, conditions to achieve sterilization can not happen. The steam purge phase mixes steam with the chamber contents, heating the load in the process. The series of pulses (positive and negative) removes about 90% of the air remaining during each pulse. 100% air removal never happens completely but the percentage of air remaining is very small. Fortunately, moist, saturated steam delivered inside the chamber can be effective and lethal even with some air remaining. It takes a fairly large volume of air present before a BI will have a positive result. Most BI's will be dead by the early portion of the exposure phase. Large, dense linen loads are an air removal challenge as well as complex medical devices with small lumens. A large metal load creates condensation but not much of an air removal challenge. During the preconditioning phase, the pressure pulses have specific transition points as part of the validated software.

### *Heat Up*

The heat up phase should be designed to minimize overshooting the selected temperature. This may require "ramping" the temperature as it gets close to the selected temperature. A slow heat up phase might add cycle time but a slow heat up is better in order to have the load at temperature at the beginning of the Exposure Phase. This avoids temperatures exceeding the selected temperatures by 20° F or more in upper portions of the chamber and also helps avoid superheat conditions (dry heat).

### *Exposure*

The exposure phase is controlled by measuring the temperature at/in the drain, the theoretical coldest spot. With the jacket temperature hotter than the selected chamber temperature, the software modulates the steam from the jacket to the chamber, much like your house thermostat, and controls temperature inside the chamber. Design of the chamber baffle is an important design consideration for even temperature distribution within the chamber. Temperature control at the selected temperature can be a 1/2 ° C above the set point when measured at the drain.

## *Exhaust & Drying*

The exhaust phase collapses the chamber steam and the dry phase begins once sub atmospheric pressures are achieved. It is important for optimum drying that the rate of the exhaust be quick. The key is having a successful dry phase is having the water pressure and volume connected to the sterilizer per the manufacturer specification. After about 16 minutes of timed drying, the vacuum system has pretty much finished evaporating the moisture created.

## *Fractionated*

All sterilizers cleared by the FDA for commercial distribution have cycles as described above. Perhaps you have seen medical device labeling for a cycle called “fractionated.” This is a European cycle and medical devices manufactured in Europe that have been cleared for the US market might mention fractionated cycles in their intended use instructions. The major difference is the preconditioning phase. The fractionated cycle starts off with a deep vacuum, not a positive pressure purge phase as do all US cleared sterilizers. Currently, there are no sterilizers cleared by the FDA that have the initial vacuum and any device labeling mentioning a fractionated cycles cannot be accomplished. Maybe some day though.

So, try standing in front of your sterilizer and watch a cycle progress through its phases. Pay particular attention to pressure points when a transition occurs. You might find it educational. It can also lead to further understanding the cycle print out.

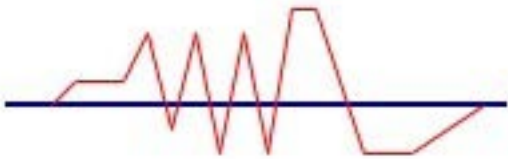
### *Gravity Flash Non Porous (unwrapped)*



### *Gravity Flash Porous (unwrapped)*



### *Dynamic Air Removal*



### *Dynamic Air Removal (SFPP)*



### *Fractionated*

