Good sterilization monitoring practices are an essential part of any healthcare sterile processing quality assurance program. Much focus has been directed toward chemical and biological monitoring of sterilization cycles; however, the first monitors that should be utilized are the steam sterilizer physical (mechanical) monitors that are integral to the system itself. These include recorders, displays, digital printouts, and gauges that display and record time, temperature, and pressure parameters of the system.

These quality-assurance monitoring tools are often underutilized or misunderstood. They provide a means to ensure that appropriate parameters are met during a steam sterilization cycle. They also give operators a record of the sterilization cycle and a method for detecting sterilizer malfunctions or sterilizer operator error.

Although physical monitors are a common part of the sterilization-monitoring process and the information provided is an important component of sterilization record keeping, many sterilizer operators do not fully understand what the data on the recording devices are telling them. It is essential that sterilizer function be closely observed and understood to ensure that the conditions inside any sterilizing chamber meet the required sterilization parameters during its operating cycle.

**Steam Sterilization Requirements**

A number of factors must be considered for successful steam sterilization of instruments and medical devices to occur. Items must first be thoroughly cleaned, properly wrapped (if applicable), and positioned correctly in the sterilizer. The sterilizer itself must be functioning correctly, the quality of steam must be acceptable, and the proper cycle type selected for the items being processed. In addition, the appropriate time and temperature for the cycle must be selected based on the recommendations from the sterilizer manufacturer. Most importantly, the medical device manufacturer's reprocessing recommendations must be followed for each device being sterilized.

The microprocessors and computer printouts available on sterilizers today monitor and provide the operator with detailed information regarding each cycle run. The examples in Figure 1 are based on information available using this type of recording technology.

**Steam Sterilizer Pressure and Exposure Temperature Relationship**

The operator must be concerned about the relationship between the chamber temperature and pressure during a steam sterilization cycle, because sterilization temperature will not be achieved without the necessary regulated steam pressure. Some sterilizer operators are confused by this relationship and reject loads because the sterilizer did not reach the pressure they felt was required.
This situation has occurred because operators have been given temperature/pressure specifications that are based on published steam tables that have not been adjusted for the actual barometric pressure at the location where the sterilizer is being used. Often, the operators are given instructions to reject loads that have not achieved a minimum steam pressure of, for example, 30 pounds per square inch gauge (psig). A single pressure level of acceptance may be applicable to a sterilizer in one location but may not be correct for a sterilizer at another location. This can lead to errors in rejecting loads that are actually perfectly acceptable.

It is important to understand all the factors that contribute to a proper evaluation of chamber pressure: the meaning of the numbers listed in published steam tables, the difference between absolute pressure and gauge pressure, and the effect of local barometric pressure on gauge readings.

Most sterilizers have displays, gauges, and printouts that indicate gauge pressure. Gauge pressure and absolute pressure are not the same. Gauge pressure indicates pressure in excess of current ambient atmospheric (barometric) pressure, whereas absolute pressure includes the current ambient pressure. In other words, gauge pressure would equal absolute pressure minus the ambient barometric pressure.

Figure 1 shows a saturated steam temperature table. The actual relationship between the temperature of saturated (100 percent) steam and chamber pressure has been well established by experimental means. Steam tables always list absolute pressure, not gauge pressure. For example, at a common sterilization temperature, 270 degrees C, the pressure shown on the steam table is 41.85 psi absolute.

When steam tables are used, a common mistake is to obtain a comparable gauge pressure by simply subtracting the barometric pressure found at sea level, which is a 14.7 psi difference. This would be correct only for equipment that is located at sea level and not for equipment at higher elevations, which have a lower barometric pressure.

To understand how atmospheric (barometric) pressure will affect the sterilizer in different locations, we will use two examples. For a hospital at sea level on the Florida coast, the barometric pressure would be about 14.7 psi. According to the steam tables, to achieve 270 degrees F (132 degrees C) requires 41.85 psi absolute pressure. To reach 270 degrees F (132 degrees C) still requires 41.85 psi absolute, but since the barometric pressure is lower, the sterilizer gauge would read a different number (41.85 minus 11, or 30.85). Again the sterilizer runs the same 2 to 3 degrees F above set point, and adding the same couple of psi as in the previous example results in a gauge pressure of about 33 psi. This is almost four psi higher than the same sterilizer operating in Florida.

Note that barometric pressure differences are not the only factor that affects the pressure required to achieve sterilization temperature. The steam tables are based on steam that is saturated, or 100 percent quality. Lesser steam quality, which is more typical, will require an even higher chamber pressure. You must have 50 psig to 80 psig of dynamic steam pressure coming from the steam source which is then regulated for your sterilization needs at the sterilizer.

Because of the variances described above and the impracticality of expecting operators to interpret barometric pressures and steam quality, a more practical way to understand what is typical for your specific sterilizer is to review your sterilizer recording devices, establish an average pressure and temperature for a particular sterilizer, and use that as a standard. If an operator observes pressures that vary by more than plus or minus 2 psi, it may be an indication that the unit calibration should be checked.

Steam pressure must be increased by a half pound for every 1,000 feet above sea level to achieve sterilization temperature; therefore, if Denver is 5,000 feet above sea level, the sterilizer may have to be adjusted by a service technician to achieve the higher operating pressure.

As you can see, atmospheric pressure alone will have a dramatic effect on a sterilizer’s required steam pressure, as will differences in steam quality. Therefore, a standardized published listing of 30 psi as the correct pressure needed for a 270 degrees F (132 degrees C) cycle is not accurate or useful to sterilizer operators.

**Understanding Prevacuum (Prevac) Sterilizer Readings**

In vacuum-assisted steam sterilizers there are three phases of the cycle with which operators should be familiar: the conditioning, sterilizing, and exhaust (drying) phases.*

**Conditioning phase:** During the conditioning phase (a “C” prints on the paper tape) the unit goes through alternating pressure and vacuum pulses (prevac cycle). The pressure pulse will always be the same — 26 psig. This is controlled by a pressure switch setting. The vacuum pulse must reach a minimum of 10 inches of mercury (Hg), and when fully

*This equipment description applies to Amsco brand equipment from STERIS Corporation. Other manufactured equipment may not be the same and the manufacturer should be consulted.
loaded, that is often the maximum level that will be achieved. Subsequent vacuum pulses (there are four) will go deeper so the operator will normally observe approximately 10 inches, then 12 inches, then 16 inches, then 18 inches. These numbers are not absolute but they give the operator an indication that the vacuum gets deeper. Smaller loads will allow the unit to pull an even deeper vacuum.

The sterilizer operator should watch for vacuum levels that remain only between 10 inches or 11 inches. This would indicate that either the sterilizer is overloaded or that the vacuum system is struggling. If this is observed, loading of the sterilizer should be evaluated and/or a service call should be initiated to have the sterilizer checked.

Excessively long conditioning phases could also be an indication of a potential problem. The sterilizer control system will allow a significant amount of time before it will sound an alarm or indicate that a cycle has been in the conditioning phase too long. If this occurs, operators should examine their typical cycle printout tapes and graphs, and establish an average time for their particular sterilizers and loads. This should run approximately 20 minutes. A time variation of a couple of minutes is not a problem, but a variation of 10 to 15 minutes for identical size loads could indicate a problem. If longer than average conditioning phases are observed, then a service call should be initiated.

Sterilizing phase: During the sterilizing phase (an “S” prints to mark the phase) in a normal 270 degrees F (132 degrees C) cycle, the first print on the recording device will indicate 270 degrees F (132 degrees C), while subsequent recordings during this phase will be at a higher temperature. Some sterilizer models will override to approximately 273 degrees F for the remaining sterilize phase (“S”) prints, while other units will only reach 271.5 degrees F. The important thing is to ensure that the subsequent prints during the sterilization phase are actually higher than the first “S” print. If the subsequent “S” prints are just barely above 270 degrees F (for example at 270.2 degrees F), then there may be an adjustment problem with the pressure regulator. This fault would be more common on older sterilizer units because the regulator (Hi-Lo valve) is accessible to operators and may have been incorrectly set. In some cases all the operator may need to do is turn the Hi-Lo valve handle a little more clockwise. Newer sterilizers do not have adjustable Hi-Lo valves and this situation would not apply.

Exhaust (drying) phase: There will only be two recorder printings during the exhaust phase, one at the beginning and one at the end. The most important thing to observe is the vacuum level achieved at the end of the exhaust phase. The vacuum should be a minimum of 25" (although elevation will also come into play here—in areas of higher altitude such as Denver, you may only see 20 inches). Again, you should establish an average for the unit, and call for service if the vacuum level varies by two to three inches for cycles with comparable loads and drying times.

### Gravity Displacement Steam Sterilizers

In gravity displacement steam sterilizers the same three phases of the cycle, the conditioning, sterilizing, and exhaust phases, should be carefully observed.

Conditioning phase: Unlike prevacuum sterilization, there is not much to look at during this phase other than charge times. This is where an average charge time should be established and then variances in these times should be monitored by the operator. An indication that a sterilizer has taken too long to charge is usually caused by a defective chamber steam trap. This would also be applicable in prevacuum units.

Sterilizing phase: There is no difference between prevacuum cycles and gravity cycles during the sterilizing phase.

Exhaust (drying) phase: The exhaust phase on gravity displacement sterilizers varies from model to model. On some gravity sterilizers, the exhaust phase is the same as it is in a prevacuum sterilizer. On those units the information described for a prevacuum sterilizer will apply. However some older gravity sterilizers use a different type of drying phase that does not pull deep vacuums because it relies on the flowing of cool air over the load. The sterilizer turns on the vacuum system and opens the air inlet valve to allow air to enter the chamber. In these units there will be very little vacuum in the chamber (two inches or three inches) when running properly. If the air inlet valve is malfunctioning, or the air filter is wet, the operator would observe deeper vacuums, which will result in poor drying rather than better drying.

### Summary

A central service department’s quality assurance program depends on many elements, one of which is system monitoring information that is understood and used appropriately by personnel. In order to assure sterilization and the proper operation of their sterilization systems, sterilizer operators must thoroughly review the physical monitor recordings at the end of each steam sterilization cycle and assure that all appropriate parameters have been met for that particular cycle before removing the load from the sterilizer.

By knowing what the appropriate sterilization parameters and values should be for that system at that geographic location, and by monitoring for inconsistencies from cycle to cycle, operators will easily detect variations in normal operation. This can serve as a detector for sterilizer malfunction, and will ensure that record-keeping practices are consistent.

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For references, log on to: www.infectioncontroltoday.com

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