MesaLabs

Spore News™

Volume 6, Number 1
January 2009

John R. Gillis, Ph.D.
President

It's Time to Take the Guesswork Out of Your Sterilization Process Apply Accurate Biological and Physical Information

The last two Spore News articles addressed 1) the "Z" value and 2) the Lethality Mapper™. The Z-value is the temperature coefficient. This value allows the user to properly correlate the effect of process temperature change on the lethal rate of spore inactivation. The Lethality Mapper is an Excel® add in that plots the lethal zones in the load being sterilized. This method will establish the worst case location within the load to sterilize. It is this location that must be identified and used for placement of your biological indicators.

Many users of BIs focus only on the D-value, which is a lethal rate measurement, at a single specified temperature. However, production processes do not deliver single temperature environments. Products placed into the sterilizer typically are at ambient temperature at the start of the process. The sterilizer provides the energy to heat these products to the desired temperature set-point. As the products are being heated to process temperature, one product location in the load will be the first to arrive at the desired process temperature and one product will be the last to arrive at that temperature. During the exhaust phase, individual products will cool at different rates. When the temperature coefficient Z-value is applied to each of these products, a significant difference in delivered lethality is observed. Almost all process specialists are aware of this condition, but few really appreciate the magnitude of this difference and the impact on actual measured spore lethality. It is far easier to assume it does not matter because the process is "conservative" and it will not have a "problem". Dangerous assumption.

We handle many customer complaints that have positive BIs in a "validated" process – How can that be? Accurately defined physical conditions and accurately defined biological conditions will always agree unless a catastrophic sterilization failure has occurred. A catastrophic sterilization failure occurs when a set of conditions that cannot be physically measured is picked up by the biological indicator. This is like the perfect storm in the sterilization world. An example in the steam process would be an air pocket in porous goods or in an occluded cavity in a device. An example for the ethylene oxide process would be inadequate humidification within the product. Neither of these

conditions can be measured physically. When this conflicting data occur, the process specialists who understand physical measurements and physical conditions are more likely to question the biological measurements. It is a common belief that the biological information is simply unreliable. In the proper application of any tool, its performance is always dependent on the skill of the craftsmen rather than the characteristics of the tool itself. Process specialists need to become more skilled in applying spore lethality and gain a greater appreciation for the accuracy of biological data. If spores are placed into a sterilizer and processed and come out alive there is a problem!

The equivalent process time value F allows the sterilization processing specialist to accurately integrate biological lethality rates at variable times and temperatures of the delivered process. If we improperly apply the biological equivalent conditions to the process, we inaccurately interpret the physical conditions. Spores are the only system available that accurately integrate all physical process lethality variations.

The following example is from data generated in a production sterilization cycle where the chamber contained 6,480 individual product units. The units are placed on three layers inside the chamber. The exposure time period was controlled by the $F_{T,Z}$* value and controlled at $F_{T,Z}$ = 16 minutes. This was controlled by the lowest of three chamber probes. The sterilizer control temperature was set at 121.3 $\pm$ 0.2°C. The maximum variation from set point was approximately -0.0 to 1.0°C. When we review lethality maps of the products, we observed that the equivalent process time for the various product locations ranged from 19.5 to 23.5 $F_{T,Z}$ (Figures 1, 2 and 3). On the surface these values appear quite close, a variance of 4 equivalent minutes. How does this equate to the BI lethality? If the spores have a D-value at the referenced temperature (T) of 2 minutes, then this process would deliver a 2 log difference in spore kill from the least lethal location to the most lethal location.

Consider the formula used to calculate the sterility assurance level (SAL):

$SAL^{(N_0\text{-}SLR)}$

N_0 = population of spores on BI

SLR = spore log reduction for the process

If the location selected for the BIs is a "guess" based on limited information and the location is not actually the least lethal zone, the result could be an overstatement of the SAL by 2. In other words, the probability of a non-sterile unit may actually be one in 10,000 as opposed to the desired one in 1,000,000.

It may sound good to say I'll take a 10^6 spore challenge, kill it in a half cycle, then I will have a 12 log spore reduction in the full cycle which yields an SAL $^{-6}$. Mathematically you can make this work, but it has too many assumptions about your process and will provide a false sense of security.

* $F_{T,Z}$ = is defined by the specific BI characteristics.

The load used in the above example, because of the relatively small mass/unit, heated quite rapidly but did not heat uniformly. It is not unusual to observe a range of 10 to 12 F equivalent minutes for massive products that heat slower. This range, when expressed in spore log reductions (SLR), could be 5 to 6. This translates to a potential variance in SAL of 10^{-1} to 10^{-6} throughout the load. This is why it is extremely important to identify the proper monitoring location for the BIs. Nothing can be done about the variance in $F_{T,Z}$ values due to the load mass. Identifying the worst case location in the load and properly integrating lethality is absolutely essential to accurately describe the process SAL.

This brings me to my last point. The mathematical formulas for calculating meaningful D-values require all individual data points to be statistical replicates. Statistical replicates require all BI samples to be exposed to exactly the same sterilization environment. Individual BIs randomly distributed throughout the load are not statistical replicates, but each BI is a replicate of one. This is confirmed by the lethality maps illustrating varying lethal zones in the sterilizer. If all the BI data from randomly placed samples is used to calculate a D-value, the result is a number that is meaningless. The application of this value to a process will be incorrect. Physical process data and biological measurements will never agree. The easiest explanation is to blame the spores, however, Spore's Don't Lie®!

Figure 1

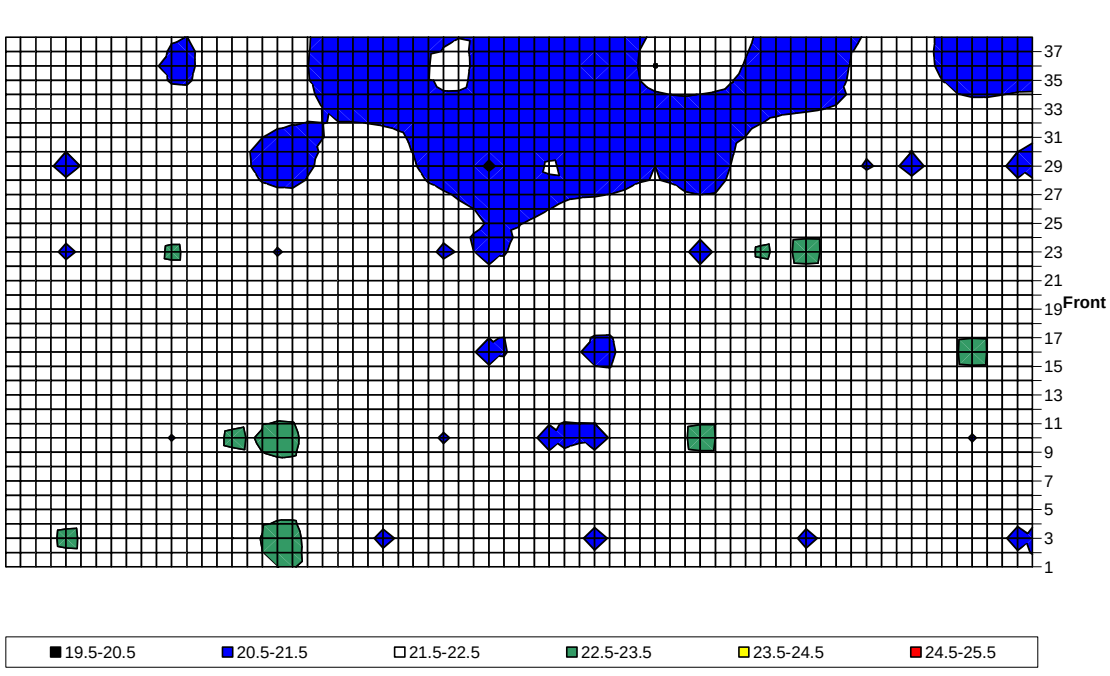


Figure 2
Level 2

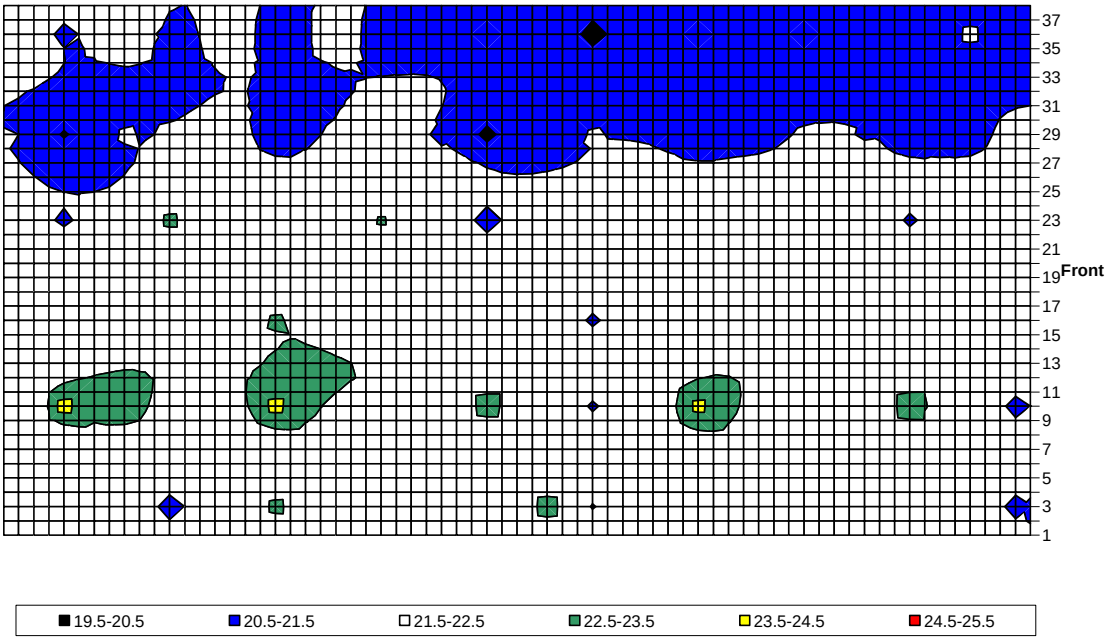
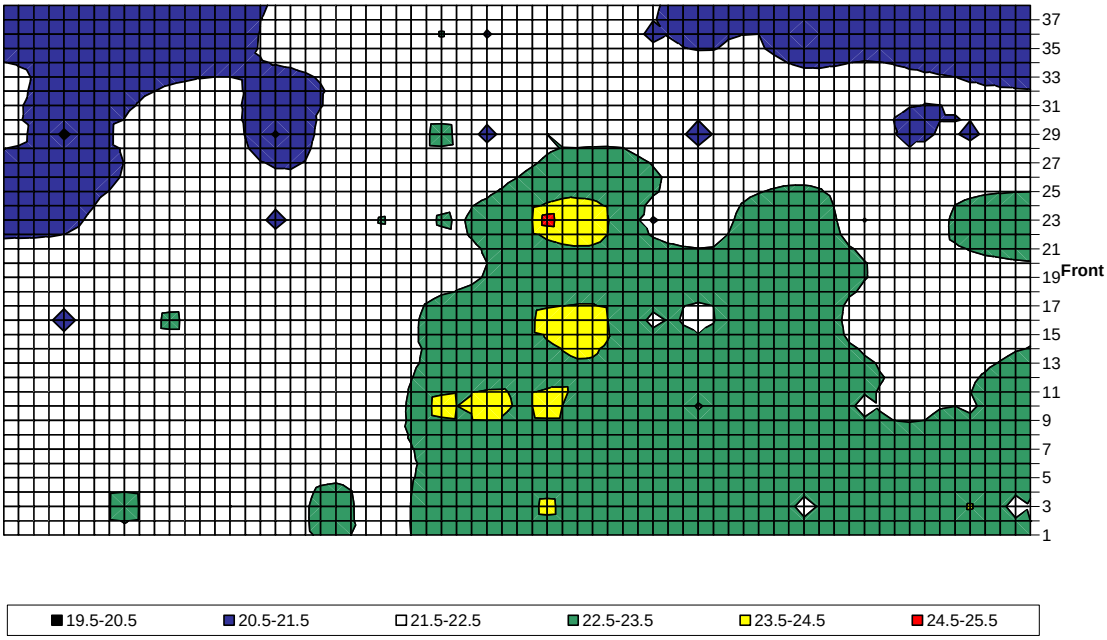


Figure 3
Level 3



If you would like to order the Lethality Mapper (Reorder # LETHMAP) please contact customer service by email at cust-service@sgmbiotech.com or by phone at (406) 585-9535 or by fax at (406) 585-9219.

SPORES DON'T LIE®

Please email us with topics you would like to see addressed in "Spore News".