Monitoring Sterilization with the Verify™ Integrator System

INTRODUCTION

The Verify line of integrators is an advanced monitoring system of inks which is capable of integrating the critical parameters of sterilization into an easily readable color reaction. It is the only system of strip integrators which has a documented color reaction that is correlated with the kill of biological indicators.[5] Verify integrators react directly with the sterilizing agent: they are not dependent on the sterilizing agent melting a chemical compound which then wicks along a medium into a visible region.

STEAM STERILIZATION

For steam sterilization to be effective, four critical parameters must be attained inside each pack sterilized:

- time,
- temperature,
- presence of saturated steam, and
- absence of air.

If any of these four parameters are lacking, sterilization may not be achieved.

Temperature sensors on the sterilizer cannot monitor these four parameters for two reasons: the sensors are located in the sterilizer drain and not inside each pack, and they only sense temperature. They cannot indicate whether steam is producing the temperature (air without moisture can also be heated to sterilizing temperatures).

Biological indicators, whether glassine-enclosed spore strips or self-contained vials, are excellent for monitoring steam sterilization cycles since they integrate the attainment of all four critical parameters into one visible display: the death of the indicating spores. But biological indicators also have limitations, i.e., they are not used inside each pack sterilized and their results are not available until after 1 day of incubation.

For these reasons, chemical integrators were developed since they were economical enough to be used inside every pack sterilized, as recommended by the JCAH, AORN, and AAMI[1,2,4] and they could be inspected immediately after a sterilization cycle.

VERIFY STEAM INTEGRATORS

All chemical integrators are not alike. Some only measure one parameter such as temperature. Others can integrate up to three parameters: temperature, presence of steam, and absence of air. A few of these types of integrators even display a preprinted reference color to aid in the interpretation of the indicator ink reaction. But most of these preprinted reference colors show to what color the indicator ink can change; they do not correlate the attainment of the end point color to any criterion of sterilization such as death of spores, full cycle time, or any other meaningful measurement of time. They simply illustrate what color the indicating ink should be whenever it reaches its full reaction.

The Verify family of integrators is an advancement over existing technology in that it has developed and documented a way of using the preprinted reference color for obtaining a useful and meaningful measure of the critical time parameter in steam sterilization. Verify steam inks, upon exposure to saturated steam at sterilization temperatures, will start changing from a yellow to a brown color. The longer correct sterilizing conditions exist at the site of the Verify integrator, the darker the brown color that develops on the integrator. Air, the most frequent cause of steam sterilization failure, can block the color development of Verify inks.

Verify integrators, however, are the only strip integrators that have correlated the color of their ink reaction with the death of *Bacillus stearothermophilus* spores, the recommended biological challenge for monitoring steam sterilization.[3] Development of this system entailed placing both Verify ink integrators and biological indicators next to each other, and then simultaneously exposing both types of integrators to various steam sterilization conditions. After each test, the intensity of the ink color was measured with a densitometer, and the biological indicator was cultured for viability of spores.

After thorough experimentation in 250°F gravity and 270°F pre-vacuum cycles, it was noticed that if the biological indicator did not yield any surviving spores, the indicator inks were a particular color or darker. Conversely, if there were spores surviving after a steam exposure, the reacted indicator inks were lighter than that particular color. Using these data, the particular color was formulated into a reference color and printed on each integrator of the Verify steam system. This reference standard showed that if the indicating ink reached or turned darker than the preprinted reference color, this indicated the time at which there would be no spores surviving the steam exposure.

The Verify steam integrator was not designed to merely tell users the number of minutes their packs were exposed to a steam cycle. The integrator can, however, tell them whether saturated steam was present inside the pack for a sufficient period of time that, if a biological indicator were located next to the Verify integrator and then cultured, no positive culture would be obtained.

The actual time it takes to reach this point inside a pack depends on sterilization cycle parameters, pack and load size, and pack and load density. Integrator reaction color will match the reference color (indicating spore inactivation) sooner inside a small pack or during a 270°F pre-vacuum cycle than inside a large, dense pack or during a 250°F gravity cycle since spore-killing conditions are reached sooner inside a small pack or during the pre-vacuum cycle. In this manner, the Verify steam integrator system provides users with integrators that monitor, in a meaningful fashion, all four critical parameters that are necessary to achieve sterilization inside every pack processed by saturated steam.

Table 1 is a comparison chart that evaluates the various types of steam indicators.

ETHYLENE OXIDE STERILIZATION

The critical parameters associated with ethylene oxide (EO) sterilization are time, temperature, presence of adequate EO levels, and presence of adequate water vapor levels (relative humidity). Just as entrapped air is the most frequent cause of steam sterilization failure, lack of adequate moisture levels inside packs is the most frequent cause of EO sterilization failure.

The various sensors and probes on an EO sterilizer cannot indicate whether correct sterilizing parameters are present inside every pack processed. In fact, almost no hospital sterilizer has the capability of monitoring relative humidity levels inside a chamber. Compounding this problem is the fact that some EO sterilizers have no means of adding any moisture into the chamber, even when the prepared packs and the ambient air are very dry.

Biological indicators, utilizing spores of *Bacillus subtilis* as the challenge, are the recommended biological monitoring agents for EO cycles.[3] These biological indicators, through the death of spores, can display the attainment of all the critical parameters necessary to achieve sterilization. But just as with steam biological indicators, EO biological indicators are not routinely placed inside each pack processed, and they also do not provide their results until after several days of incubation.

VERIFY EO INTEGRATORS

To satisfy the need of obtaining results in a shorter period of time and to obtain them economically from inside each pack sterilized by EO, various types of chemical integrators were developed. Not all of these integrators are able to monitor the full spectrum of conditions present inside an EO sterilizer. Some indicate the presence of EO gas, a few are able to indicate lack of adequate moisture. Some have preprinted reference colors, but again these color references show to what color the indicator ink will turn after full reaction. They do not correlate this color reaction to any meaningful criterion of time or to the biological indicator.

The Verify EO integrator system is the only group of EO-sensitive ink indicators that has developed and documented the relationship between indicator ink reaction and spore death.[5] Verify EO inks, upon exposure to correct sterilizing conditions, turn from an off-white color to a brown color.

Table 1

Steam Indicators

Parameters	Tape	Glass Ampule	Regular Strip	Wicking Indicator	Verify Integrator Strips
Differentiates steam from air	Yes	No	Yes	Yes	Yes
Reference color	No	No	Some	Yes	Yes
Correlated with spore kill	No	No	No	Yes	Yes
Cost-effective	Yes	No	Yes	No	Yes*

*Verify steam integrators usually cost significantly less than wicking indicators, yet can provide more information.

If Verify integrators and biological indicators are exposed simultaneously, a time will be reached when the biological spores will become inactive. At this moment of spore kill, there is a particular color of brown on the Verify reactive ink. This particular brown color was measured, formulated into a reference color, and printed on each Verify integrator. During sterilization, when the indicator ink turns as dark as or darker than the preprinted reference color, there will be a corresponding absence of spore viability in the biological indicator. In other words, if a Verify integrator is placed inside a pack and then processed, and upon inspection the reactive indicator ink has turned darker than the preprinted reference color, this means that conditions inside that pack were such that if a biological indicator were present in the pack and then cultured, there would be no growth of spores from that biological indicator.

In this manner, all the critical parameters necessary for successful EO sterilization are not only monitored, but are also correlated to biological kill inside each pack. While the critical time parameter is not measured in chronological units of minutes, it is directly measured as a unit of time at sterilizing conditions that can result in the kill of spores.

Table 2 is a comparison chart that evaluates various types of EO integrators.

CONCLUSION

The Verify steam and EO monitoring system is an advanced group of sterilization integrator products that relies on the reaction of highly sensitive inks with sterilizing agents. This sensitive, color-producing ink reaction has been correlated to the death of biological indicator spores. Each integrator of the Verify system is preprinted with a colored reference standard. The color of the reference standard is such that if the indicator ink turns as dark as or darker than this color reference, then a biological indicator would also yield a negative spore culture had it been in a position next to the Verify integrator. In this manner, critical parameters, including time, are monitored inside each pack containing a Verify integrator. Considering the information provided by this comprehensive integrator system and the low cost of these integrators, the Verify integrator system is one of the most cost-effective medical devices available to the hospital today.

The contents of this document are based on the results of carefully designed studies conducted by STERIS Corporation.

References

1. AORN Recommended Practices for Inhospital Sterilization. AORN Journal 32: 222-246, 1980
2. Association for the Advancement of Medical Instrumentation (AAMI). Good Hospital Practice: Steam Sterilization and Sterility Assurance. Arlington, VA, 1980
3. Biological Indicator for Ethylene Oxide and Steam Sterilization. Paper Strip. The U.S. Pharmacopeia, 21st Ed., pp. 119-222, 1985
4. Joint Commission on Accreditation of Hospitals. Accreditation Manual for Hospitals. 1983 Edition, pp. 76-77.
5. Verify Steam and EO Gas Integrators. Report by Sterilization Technical Services, Inc. 1980.

Table 2

EO Integrators

Parameter	Tape	Strip	Wicking Indicator	Verify
EO presence	Yes	Yes	Yes	Yes
Lack of moisture	Poorly	Some	Yes	Yes
Correlated with spore kill	No	No	Yes	Yes
Cost-effective	Yes	Yes	No	Yes

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