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APPLICATION NOTE 6075

NEW MEMORIES BREAKING THE GAMMA BARRIER FOR MEDICAL CONSUMABLES

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Abstract: The first gamma irradiators for the sterilization of medical devices were developed in the early 1960s. Since their introduction to the medical industry, the flexibility, reliability, and versatility of gamma irradiation has led to it becoming the sterilization method of choice for single-use medical devices. According to the Canadian Nuclear Association (CNA), gamma processing to now account for at least 40% of the sterilization of all medical devices and supplies globally. Although gamma irradiation has several advantages over alternative physical and chemical methods for device sterilization, historically gamma irradiation has been incompatible with semiconductor devices that incorporate floating-gate memory technologies.

This application note compares gamma irradiation versus alternative sterilization technologies and introduces Maxim Integrated's solution for overcoming this incompatibility through the 1-Wire® DS28E80, a user-programmable non-volatile memory employing a storage cell technology with high resistance to gamma radiation.

Introduction

Today's medical instruments and their supporting equipment often incorporate single-use consumable sensors, cables, probes, and/or other peripherals to ensure sterility before making contact with the patient. In many cases these consumables can directly benefit from the addition of nonvolatile (NV) memory for embedding manufacturing characteristics, operating parameters, identification, or usage monitoring. This added electronic functionality allows for factory calibration of the consumable to the medical instrument. It also ensures the quality of the product through recording, limiting, or even preventing unsanitary reuse.

Unfortunately, these various benefits have historically not been realized when gamma irradiation is the required sterilization method for production. This is because gamma radiation is directly incompatible with semiconductor devices (ICs) that traditionally incorporate floating-gate memory technologies used in NV memories such as erasable programmable read-only (EPROM), electrically erasable programmable read-only (EEPROM), and flash. Exposure to gamma's high-ionizing radiation corrupts the logic bit values within these memories, so the relevant data programmed prior to gamma sterilization cannot be retained. Thus, designers have been forced to choose between the added functionality provided by embedded memory and the preferred sterilization method for their product.

Why Gamma Sterilization?

So what is the target sterilization level for these medical consumables, and why would a medical OEM choose to utilize gamma irradiation over other available sterilization methods such as ethylene oxide (EtO), electron beam (E-beam), or X-ray? To answer this, we begin by defining sterilization.

For medical consumables sterilization is the process of reducing pathogenic organisms that lead to disease (e.g., viruses, bacterium, prions, fungi, and protozoans) from an object's surface. For consumables that penetrate or otherwise make contact with an already aseptic part of the human body, the defined low-sterility-assurance level (SAL) is typically at least 10^{-6} or a one-million-to-(essentially) zero reduction in these microorganism populations. When properly utilized, all four sterilization methods referenced here can achieve this target SAL by destroying the DNA chains and, thus, the capacity for reproduction of these microorganisms. However, there are distinct advantages that gamma offers for high-volume, single-use consumables.

First, the process of gamma irradiation is the exposure to a Cobalt-60 source, which is a continuous production flow, making it both predictable and repeatable (i.e., reliable). The more common batch-type production flows are either subject to starts and stops to their sterilization source or require routine maintenance and validation. To understand fully, think of the subtle variances between the production lot numbers from your last paint or ceramic tile purchase. A continuous flow helps to minimize these variances that can occur in production. Secondly, with the exception of E-beam, gamma offers a shorter turnaround in total processing time. Irradiated material can be shipped immediately upon completion of exposure without additional preconditioning, aeration, or post-validation that would typically be required for EtO. In addition to this shorter and simpler processing cycle, the high penetration, wide emission angle characteristics, and minimal temperature effect of high-energy photons (gamma rays) enable sterilization over a broad range of product materials, sealed packaging types, and package sizes. There is no concern of remaining radioactivity, toxic residue, or need for further validation of sterilization after exposure.

Similarly, both E-beam and X-ray have reduced processing steps, leave no residual toxins, or need for post validation. Unlike gamma irradiation, however, E-beam cannot support the same level of penetration and, thus, is more suitable for low density, uniform products (e.g., wires and cables). Further, E-beam's significantly higher dosing rate needs to be strictly timed in order to avoid excess heat buildup or other adverse effects to the material being sterilized. While the X-ray process utilizes an E-beam directed onto an X-ray converter to create the desired high-penetrating photons, the process of converting electrons to photons is inefficient in comparison to gamma. All this makes X-ray more costly in comparison to gamma. See **Figure 1**.

Gamma irradiation was originally introduced to the medical industry in the early 1960s. Over the decades, these advantages of versatility, reliability, and affordability led to gamma's continued popularity with leading medical device manufacturers for sterilizing their single-use consumables without embedded memory (e.g., syringes, needles, cannulas).

Figure 1. Comparison of sterilization technologies.

Gamma-Resistant Memories Retain Programmable Data

Fortunately today there are user-programmable NV memory ICs that incorporate nonfloating-gate technologies and are highly resistant to gamma radiation's high-energy photon bombardment. Gamma-resistant memories like Maxim Integrated's DS28E80 1-Wire® memory are guaranteed to retain their user-programmed data beyond the 25kGy to 50kGy (kiloGray) dosage levels typically required by the medical industry for sterilization. In addition to a nonfloating-gate NV memory, the DS28E80 incorporates new layout techniques to mitigate damage to sensitive circuitry, while using proprietary nonreversible oxide state changes to ensure that user data is uncompromised by gamma exposure. Using these gamma-resistant memories, manufacturers can program the embedded memory of their consumables prior to packaging and shipping to a sterilization facility.

In addition to gamma radiation resistance, these memories routinely incorporate features such as unique factory-programmed identification numbers and user-reprogrammable memory blocks with options of write protection. With this electronic serialization, flexibility of the memory, and high gamma resistance, the gamma-radiation-resistant memories like Maxim Integrated's DS28E80 give medical device manufacturers both the electronic functional benefits of NV memory for their single-use consumables *and* the production advantages that gamma irradiation offers for sterilization. Memory *is* breaking the gamma barrier.

1-Wire Gamma Radiation Resistant Memory

The DS28E80 is a user-programmable nonvolatile memory chip that employs a storage cell technology that is highly resistant to gamma radiation, making it ideal for applications that require embedded memory to be programmed prior to packaging and sterilization of the end product in which it is used. In addition to this high gamma resistance, the DS28E80 memory is organized in 8-byte blocks. Each block can be independently write-protected providing greater flexibility in programming the user memory. The DS28E80 communicates over a single-contact 1-Wire bus with each device having its own guaranteed unique 64-bit serial number that is factory programmed into the chip. With this serialization, flexibility of the memory, and high gamma resistance, the DS28E80 not only supports the memory needs for single-use medical devices, but does so through a single, dedicated contact when interconnect must be minimized.

Key DS28E80 Features Include:

- Gamma Radiation Resistant Up to 75kGy (kilo Gray)
- Single-Contact 1-Wire Interface Minimizes Interconnect Between a Sensor and Instrument
- Reprogrammable 248 Bytes of User Memory
- Flexible Write-Protection Options for Use Memory
- Unique Factory-Programmed, 64-Bit Identification Number
- Automatically Calibrates Sensors or Consumables

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Related Parts		
DS28E80	Gamma Radiation Resistant 1-Wire Memory	Free Samples

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