Related Parts: DS28E80, DS28E83, DS28E84

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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 International Irradiation Association (iia), gamma processing to now account for at least 40% of the sterilization of all single-use 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 solutions for overcoming this incompatibility using the DS28E80 and DeepCover® secure authenticators DS28E83 and DS28E84,

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., small sensors and catheters). 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).

Sterilization Technologies				
	Gamma	X-ray	Electron Beam	Ethylene Oxide
Process Type	Continuous	Continuous	Continuous	Batch
Process Phases	Exposure	Exposure	Exposure	Pre-conditioning Exposure Aeration
Product Design	No orientation or density restrictions	No orientation or density restrictions	Density, size, and orientation must be considered	Cannot have any sealed cavities
Product Packaging	No restrictions	No restrictions	Low density, uniformly packaged	Must be gas-permeable or include 2nd sealing process. Must withstand expansion during vacuum.
Process Variables	Time (hours: total based on dose requirement)	Time (hours: total based on dose requirement) Electrical Parameters	Time (minutes: total based on dose requirement) Conveyer speed Electrical Parameters	Time (hours: total based on product material) Temperature Pressure Humidity Gas Concentration Electrical Parameters
Penetration	Complete penetration	Complete penetration	Dependent upon proper density, size, and orientation	Dependent upon proper packaging
Product Release	Dosimetric release	Dosimetric release	Dosimetric release	Biological indicators or parametric release to verify sterility assurance level (SAL)
Material Compatibility	Most materials are satisfactory. Though can be incompatible with PVC, Teflon®, and Acetal	Most materials are satisfactory. Though can be incompatible with PVC, Teflon, and Acetal	Most materials are satisfactory	Nearly all materials are compatible
Residuals	None	None	None	Possible ethylene oxide and ethylene chlorohydrin, requiring aeration period following processing

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 20kGy to 30kGy (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 can incorporate features such as unique factory-programmed identification numbers, user-reprogrammable memory blocks with options of write protection, and, for the DS28E83 and DS28E84, secure usage management and counterfeit protection through elliptic curve digital signature algorithm (ECDSA) and Secure Hash Algorithm (SHA-256) based cryptographic authentication. With this electronic serialization, flexibility of the memory, high gamma resistance, and available secure authentication, the gamma-radiation-resistant memories like Maxim Integrated's DS28E80, DS28E83, and DS28E84 give medical device manufacturers the electronic functional benefits of NV memory and crypto secure authentication for their single-use consumables and the production advantages that gamma irradiation offers for sterilization. Memory is breaking the gamma barrier.

1-Wire Radiation Resistant ICs

The DS28E80, DS28E83, and DS28E84 are ICs that employ memory storage cell technology that is highly resistant to gamma and E-beam radiation, making them ideal for applications that require embedded memory to be programmed prior to packaging and irradiation sterilization of the end product in which they are used. In addition, the DS28E83 and DS28E84 provide symmetric key SHA-256 and public key ECDSA secure authentication to protect patients against the risks associated with non-qualified counterfeit devices or possible incidental overuse or re-use.

These devices communicate over the Maxim 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 serialization, flexibility of the memory, high radiation resistance, and secure authentication, these devices not only support the memory needs for single-use medical devices but do so through a single, dedicated contact when interconnect must be minimized.

Key Shared Features Include:

- Radiation Resistant Up to 75kGy (kilo Gray)
- Single-Contact 1-Wire Interface Minimizes Interconnect Between a Sensor and Instrument Programmable Non-Volatile User Memory
- Flexible Multiple Protection Options for Use Memory
- Unique Factory-Programmed, 64-Bit Identification Number

Additional Features for the DS28E83 and DS28E84:

- ECC-P256 Compute Engine
    - FIPS 186 ECDSA P256 Asymmetric Signature and Verification
    - ECDH Key Exchange for Optional Session Key Establishment
    - ECDSA Authenticated R/W of Configurable Memory
- SHA-256 Compute Engine
    - FIPS 180 SHA-256 Digital Signature
    - FIPS MAC for Secure Download/Boot
    - FIPS 198 HMAC for Bidirectional Authentication and Optional GPIO Control
- TRNG with NIST SP 800-90B Compliant Entropy Source with Function to Read Out

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