



The Effects of Cosmic Radiation on Implantable Medical Devices

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Metal oxide semiconductor(MOS) integrated circuits, with the benefits of low power consumption, represent the state of the art technology for implantable medical devices. Three significant sources of radiation are classified as having the ability to damage or alter the behavior of implantable electronics; Secondary neutron cosmic radiation, alpha particle radiation from the device packaging and therapeutic doses(up to 70 Gy) of high energy radiation used in radiation oncology.

The effects of alpha particle radiation from the packaging may be eliminated by the use of polyimide or silicone rubber die coatings. The relatively low incidence of therapeutic radiation incident on an implantable device and the use of die coating leaves cosmic radiation induced secondary neutron single event upset(SEU) as the main pervasive ionising radiation threat to the reliability of implantable devices. The most sensitive circuit structure within a typical microcomputer architecture is the RAM due to the small amount of charge used to store information. Those systems in which critical controlling software is in RAM, as opposed to ROM, are especially prone to SEUs in the form of memory bits changing state. In this case, single bit upsets should be corrected via a memory error detection and correction scheme.

A theoretical model which predicts the susceptibility of a RAM cell to secondary neutron cosmic radiation induced SEU is presented. The pacemaker and implantable cardioverter defibrillator (ICD) market demand high device longevity to avoid the patient discomfort and risk associated with device replacement. However, the model indicates that reducing supply voltage, to increase device longevity, leads to an exponential rise in SEU sensitivity. Furthermore, the resistive load NMOS memory cell modeled in this work has a higher sensitivity to upset than comparable CMOS cells due to the contribution of diffusion in the charge collection process. As part of the model development a previously unreported method for calculating the collection efficiency term in the upset model is presented along with an extension of the model to enable estimation of multiple bit upset rates. Shielding considerations unique to the implantable device were also considered.

An ICD is used as a case example to demonstrate model applicability and test against clinical experience. A total of 579 devices are included in this study, implanted in patients in 53 different cities and 10 different countries worldwide. The model correlates well within the statistical uncertainty associated with both the theoretical and field estimate. The predicted Soft Error Rate(SER) is 4.8×10^{-12} upsets/(bit hr) compared to an observed upset rate of 8.5×10^{-12} upsets/(bit hr) from 20 upsets collected over a total of 284672 device days. Note, that the predicted upset rate may increase by up to 20% when consideration is given to patients flying in aircraft. The upset rate is also consistent with the expected geographical variations of the secondary cosmic ray neutron flux, although insufficient upsets precluded a statistically significant test.

In summary, the consistency between model calculations and clinical and experimental observations is convincing evidence that the observed single and multiple bit upsets are attributable to secondary neutron cosmic radiation. This is the first clinical data set obtained indicating the effects of cosmic radiation on implantable devices. Importantly, it may be used to predict the susceptibility of future implantable device designs to the effects of cosmic radiation.