X- and Gamma-Ray Hardness of Floating-Gate EEPROM Technology as Applied to Implantable Medical Devices

David Prutchi, Member, IEEE, John L. Prince, Fellow, IEEE, and Lawrence J. Stotts, Member, IEEE

Abstract—There is a growing need for the inclusion of nonvolatile memory within implantable medical devices in order to store product identification, operating parameters, calibration information, as well as patient and diagnostic data. Due to the critical nature of the application however, the data retention reliability is of utmost importance. In the case of nonvolatile memory, a source of concern regards their exposure to ionizing radiation as the result of diagnostic or therapeutic procedures performed on the patient. This paper reports on X- and gamma-ray experiments and calculations on a representative modern electrically erasable and programmable read-only memory (EEPROM) (Atmel 24C64).

No transient upsets due to 150 kVp X-rays were observed in 10 unbiased and five biased DTU’s up to the maximum achievable 27 rad(Si)/s for a total dose of 200 rad(Si). Unbiased parts had no failure to an average total-dose of 40.9 krad(Si). The lowest failure level observed for an unbiased part was 30.0 krad(Si). In the biased parts, the read-mode operating current increased as a function of total dose from 47 μA prior to exposure to 385 μA at 30 krad(Si). The mean highest no-failure level for 10 unbiased parts exposed to Co^10 gamma-rays was 36.9 krad(Si) with a sigma of 2.3. Five biased DUT failures occurred at a mean of 27.84 krad(Si) with a sigma of 2.42.

The analysis of these data, in comparison to maximum therapeutic photon radiation doses suggest that floating-gate EEPROM technology is reliable in the presence of photon ionizing-radiation exposures typical of medical diagnostic and therapeutic environments.

Index Terms—EEPROM, implantable biomedical devices, integrated circuits radiation effects, radiation hardening.

I. INTRODUCTION

Modern implantable medical devices such as implantable pacemakers, automatic cardioverter defibrillators, drug pumps, and neural stimulators are battery-operated devices which operate under the control of an internal low-power microprocessor [1]. In general, the operating code for the devices is fully based on ROM, since the contents of volatile memory can be lost or corrupted due to power glitches caused by extreme temperatures prior to implantation, inappropriate operation due to electromagnetic interference and transients (e.g., electrosurgery, external defibrillation), as well as due to faults caused by exposure to ionizing-radiation (e.g., diagnostic X-rays and radiotherapy).

In spite of this, different implantable medical device products belonging to a single product family may require customization without hardware modifications to their common underlying platform. To make this possible, electrically erasable and programmable read only memory (EEPROM) technology has been proposed as a practical solution for the nonvolatile storage of configuration and identification information.

In addition, nonvolatile storage of parameters and data for implantable medical devices would open up a number of other possibilities including software-based trims and calibrations (e.g., reference voltage trim, real-time-clock calibration, etc.), storage of programmed therapy parameters for automatic recovery from fault conditions, as well as storage of patient data, including selected items of the patient’s medical history.

Commercially-available EEPROM integrated circuit (IC) die or custom IC cells have been shown to be sufficiently reliable for storage of data within active implantable medical devices. For example, 30 parts of a representative sample of commercially-available EEPROM’s (Atmel 24C04) were submitted to life testing, and all parts passed the subsequent electrical tests. In addition, 15 parts of the same IC were subjected to mechanical shock tests, passing the post-shock electrical tests. Another 15 parts passed all tests after being subjected to mechanical vibration, temperature cycling, and temperature shock.

Considering the importance of the data to be stored however, reliable data retention is a matter which deserves added scrutiny. As such, an issue that immediately comes to mind when designing with charge-storage devices is their susceptibility to ionizing radiation. This paper reviews available literature and discusses tests conducted to determine the ionizing-radiation endurance characteristics for EEPROM technology as applicable to their use in implantable medical devices.

II. EEPROM OPERATION AND ENDURANCE CHARACTERISTICS

As shown in Fig. 1, a floating-gate EEPROM cell comprises a FET transistor with a gate electrode floating within a silicon
oxide layer. To erase or write the cell, one of the selection transistors (e.g., row select transistor) conducts a high potential (approximately 20 V). This high voltage allows electrons to migrate or tunnel through the silicon oxide either into or out of the polysilicon floating gate. To allow single-supply operation, a self-contained charge-pump is employed to generate the high voltage required for erase or write operations.

The only difference between an erase state and a write state is the absence or presence of charge in the polysilicon floating gate. To achieve an erase operation, +20 V are applied to the polysilicon memory cell gate and 0 V to the bit line drain (e.g., column), causing electrons to tunnel from the substrate through the tunnel-dielectric oxide into the polysilicon floating gate until the polysilicon floating gate is saturated with charge. To achieve a write operation, the polarity is reversed (20 V to the bit line drain and 0 V to the memory cell gate) such that electrons tunnel from the polysilicon floating gate through the tunnel-dielectric oxide to the substrate. A complete sequence of charge transfer onto the floating gate (erase) and the electrical removal of that charge (write) is defined as one ERASE/WRITE (E/W) cycle.

As additional E/W cycles occur, the continued application of this electric field begins to wear out the EEPROM cell tunnel-dielectric oxide. Over the cell’s application lifetime, as measured by the number of E/W cycles, the EEPROM cell wears out because of the field stress causing charge trapping of electrons within the tunneling-dielectric oxide. Field stress wear-out is a cumulative effect. As the sum of total E/W cycles increases, more and more charge is trapped, and EEPROM cell wear manifests itself as a decrease in cell output voltage. At the failure point, the cell output voltage is so low that the associated sense amplifier is incapable of differentiating between an erase and a write state during a read operation.

As such, "endurance" is defined as the number of times that an EEPROM cell may be successfully erased and written to without resulting in erroneous data. For example, in the case of a representative modern EEPROM (Atmel AT24C64), endurance is guaranteed to be 100,000 E/W cycles and 40 year data retention. This endurance is specified at \( V_{cc} = 5 \) V over the entire temperature range (−40 to +85 °C).

Qualification data provided by Atmel [2], [3] for data retention and write endurance for a population of 284 AT24C64 EEPROM IC’s shows that its process has a ten-year cumulative failure of 0.06%, an MTBF of 167 × 10^6 h, and a failure rate of 6.0/billion h (6 FIT’s or 0.0006%/1000 h). These estimates assume random failures, 0.5 eV activation energy, 50 °C ambient operation and 60% upper confidence level. The E/W endurance reported by Atmel for the AT24C64 has been one single bit failure at 100,000 E/W cycles, and wearout between 1.2–4 M cycles.

Endurance can be increased beyond the guaranteed point by keeping the application temperature during E/W cycles as low as possible, as well as by keeping the \( V_{cc} \) voltage on the EEPROM as low as possible whenever an E/W cycle occurs. In the intended operating environment of an active implantable medical device, temperature should remain constant at approximately 37 °C. Using an EEPROM endurance model developed by Microchip Technologies [4], the endurance of the AT24C64 can be estimated to increase at 37 °C to approximately 600,000 E/W cycles. It must be noted that READ operations under normal operating conditions are unlimited since they impose virtually no stress on the cell. It is only those operations which apply high voltage across the tunnel-dielectric oxide (i.e., erase and write) that impact EEPROM endurance [5].

As shown in Fig. 2, when EEPROM cells are exposed to ionizing radiation, charge trapping of electrons within the tunneling-dielectric oxide is increased, and the results appear as premature field stress wear-out. Obviously, this process will be most vigorous when a large potential is applied across the tunneling dielectric oxide. and previous work [6] has shown that floating-gate EEPROM's are most vulnerable to ionizing radiation during E/W cycles.

A number of studies have been conducted to determine the effects of radiation on EEPROM's. These studies have been carried out mainly for the DoD, DoE, and NASA due to their peculiar mission requirements. Unfortunately however,
published data are not directly applicable to the newer small-geometry (1.5 μm) technology used in EEPROMs such as the AT24C64, but they hint at its appropriateness for application in implantable medical devices. For example, Snyder et al. [7] found that late 1980's-vintage floating-gate EEPROM's withstood approximately 100 krad(Si) before failure.

Wrob Les [8] reported that the Cobalt-60 (Co-60) gamma-radiation total-dose biased failure level for a SEEQ Technologies 28C256 EEPROM was mode-dependent, i.e., 33 krad(Si) for reading and 9.5 krad(Si) for writing. The write-mode failure was also reported to be dose-rate dependent, increasing from 10 krad(Si) at 11 to 28 krad(Si) at 0.1 rad(Si)/s. Average upset and latch-up thresholds were reported at 3.8 × 10^8 rad(Si)/s and 7.7 × 10^8 rad(Si)/s, respectively. Memory contents for this device were retained following exposure up to 108 krad(Si) and following 10^12 rad(Si)/s.

Bumbaugh and Rosario [9] reported biased total-dose Co-60 failure was induced within the range of 1.0 krad(Si) (Xicor X28C256) to 13 krad(Si) (Seqeq CM28HC256) during write procedures, and between 4.5 krad(Si) (Xicor X28C256) to 71 krad(Si) (Seqeq CM28HC256) for read procedures. Unbiased failures occurred in the range of 7.9 krad(Si) (Seqeq DQ28C256) to >53.4 krad(Si) (Xicor X28256). A sharp increase in standby current was also observed as the total dose of unbiased parts approached the read-mode failure level (from 21 times to over 158 times the pre-irradiation values). Similarly, the address access time increased significantly in these parts (from 1.4 to 4.7 times the pre-irradiation value).

The same authors reported that flash x-ray dose rates of up to 2.6 × 10^10 rad(Si)/s did not cause data upsets in any of the tested 28C256-type complementary metal-oxide-semiconductor (CMOS) EEPROM's. However, some latchups were observed at 5.4 × 10^9 rad(Si)/s, and parts started to draw considerably larger currents.

Tests conducted by SAVEInc (Placentia, CA) for Atmel in 1991 demonstrated that their 32K × 8 EEPROM (an AT28HC256, similar to the devices tested by Bumbaugh and Rosario [9]) showed no functional failure to the highest total dose tested of 16 krad(Si). In the same parts, transient effects were observed for dose rates higher than 2 Mrad(Si)/s.

In general, failures for a part occur at higher total-doses for unbiased parts than for biased parts. To take advantage of this fact, EEPROM's used as "shadow" storage for volatile registers within an implantable medical device can remain unbiased most of the time, with brief periods of activity limited to times when the contents of the volatile registers are to be verified or restored.

III. EXPERIMENTAL PROCEDURE

In order to obtain engineering evaluation data relevant to a representative modern floating-gate EEPROM technology, a series of tests were conducted to provide data regarding the performance of these integrated circuits under realistic medical diagnostic and therapeutic radiation environments.

The tests conducted were designed to comply with the following requirements:

1) determine the effects of ionizing radiation on the data retention characteristics and overall endurance of the Atmel AT24C64 EEPROM IC's;
2) determine the dose-rate and total dose threshold after which transient and/or permanent changes occur in the IC's. These changes included bit errors or deviation
TABLE I

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vol. 1</td>
<td>Output Low Voltage Level $V_{cc} = 3 \text{ V}$, $R_{load} = 1.2 \text{ k}$Ω</td>
<td></td>
</tr>
<tr>
<td>Vol. 2</td>
<td>Output High Voltage Level $V_{cc} = 1.8 \text{ V}$, $R_{load} = 10 \text{ k}$Ω</td>
<td></td>
</tr>
<tr>
<td>$I_{dd}$</td>
<td>Input Leakage Current $V_{in}$, $V_{cc}$ or $V_{ss}$</td>
<td></td>
</tr>
<tr>
<td>$I_{ds}$</td>
<td>Output Leakage Current $V_{out} = V_{cc}$ or $V_{ss}$</td>
<td></td>
</tr>
<tr>
<td>$I_{ss}$</td>
<td>(Standby) Standby Supply Current $V_{cc} = 3 \text{ V}$ &amp; 1.8 V, $I_{out} = 0A$</td>
<td></td>
</tr>
<tr>
<td>$I_{sc}$</td>
<td>(Active) Operating Supply Current $V_{cc} = 3 \text{ V}$ &amp; 1.8 V, read mode</td>
<td></td>
</tr>
</tbody>
</table>

from established electrical characteristics (data retention characteristics and overall endurance).

The radiation source used for the X-ray tests was a Norelco MG150 unit fitted with a 150 kVp beryllium window tube. Gamma-ray exposure was achieved using a 30 kCi model 109 Co⁶⁰ immersion source manufactured by J. L. Shepherd. For doses between 10 rad(Si) and 1 Mrad(Si), the outputs of these sources were calibrated using thermoluminescent dosimeters. Calibration of the Co⁶⁰ source was done with the dosimeters placed in a Pb/Al enhancement shield. For lower doses, a calcium fluoride capsule and a Victoreen 2810 reader were used for calibration.

For X-ray transient upset tests, a device under test (DUT) was placed as close to the source as possible to receive maximum dose rate without upsetting the DUT test temperature of 37 °C. To separate possible transient upsets from total-dose-caused errors, each exposure was limited to 200 rad(Si).

Upon completion of the transient upset test, a total-dose effect test from the same X-ray source was conducted. DUT samples were placed in a location where multiple samples received a homogeneous dose of radiation. For the total-dose test, five DTU's were tested in situ, where samples were biased and exercised during irradiation. The rest of the samples were irradiated unbiased. The unbiased samples were tested for their functionality and memory integrity at every 3 krad(Si) interval up to 40 krad(Si). The electrical parameters shown in Table I were also measured every 3 krad(Si) intervals for all samples, including the in situ test samples. Exposure to the Co⁶⁰ source was performed in the same manner.

Reading and programming of the DUT were done by a SUPERPRO™ programmer through custom driver hardware. The dynamic supply current to the DUT was measured by a digitizing oscilloscope (Tektronix TDS350) using a 100 Ω shunt resistor.

Static electrical parameters (leakage currents and standby supply current) were measured with two supply voltages: 1.8 and 3 V. The input leakage current ($I_{dd}$) was measured at the SCL (serial clock) pin of the AT24C64 IC, and the output leakage current ($I_{ds}$) was measured at the SDA (serial data) pin; both using a Keithley 485 pm. The standby current ($I_{ss}$) was measured with a Fluke 45 DMM.

The DUT's output low voltage level ($V_{dd}$) was measured dynamically since during operation, the SDA pin cannot be latched at logic-low level for extended periods of time. To do so, a load resistor on the SDA pin simulating the manufacturer's output current condition was used as a pull-up resistor. The voltage at this pin was monitored using a digitizing oscilloscope (Tektronix TDS350) triggered by a high-to-low transition on the direction control signal of the SUPERPRO™ programmer. $V_{dd}$ was measured using supply voltages of 1.8 and 3 V.

IV. RESULTS

A. X-Rays

For 150 kVp X-rays, the following data was obtained.

1) No transient upsets were observed in either the ten unbiased or five biased (in situ) parts for any dose rate up to the maximum achievable with the X-ray machine used [27 rad(Si)/s for a total dose of 200 rad(Si)]. No significant parametric changes were observed after exposure.

2) The total-dose results showed that the unbiased parts had no failure (data corruption) up to an average of 40.9 krad(Si). When the parts showed data corruption, they could not be properly read at 1.8 V. However, the correct information could be retrieved at higher operating voltages. The lowest failure level observed for one unbiased part was 36.0 krad(Si).

3) Keeping in mind that only ten parts were used for the unbiased tests, the log-normal statistics of 50/90 are 38.6 krad(Si) and 99/90 of 26.8 krad(Si).

The “50/90” value is the value for which we are 90% confident that at least 50% of the population has a failure threshold greater than that value. The “99/90” value is the value for which we are 90% confident that at least 99% of the population has a failure threshold greater than that value.

4) As shown in Fig. 3(a), standby current (50/90 log-normal statistic, 40 krad(Si) total dose) changed from 400 nA by 315 nA at $V_{cc} = 1.8 \text{ V}$ and from 7.2 μA by 3.41 μA at $V_{cc} = 3.0 \text{ V}$. As shown in Fig. 3(b), active current (50/90 log-normal statistic, 40 krad(Si) total dose) changed from 39.1 μA by 5.97 μA at $V_{cc} = 1.8 \text{ V}$ and from 157 μA by 8.84 μA at $V_{cc} = 3.0 \text{ V}$. Shifts in other electrical parameters were not significant.

5) Only one out of five biased parts showed data corruption at a tested level [to 40 krad(Si)]. This one part failed at 30.0 krad(Si), placing the 50/90 log-normal statistics at 34.0 krad(Si) and 99/90 log-normal statistics at 19.0 krad(Si).

6) The standby and read-mode operating currents in the biased parts increased considerably as a function of total dose. As shown in Fig. 4(a), standby current (50/90 log-normal statistic, 40 krad(Si) total dose) changed from 400 nA by 811 nA at $V_{cc} = 1.8 \text{ V}$ and from 7.3 μA by 1.14 μA at $V_{cc} = 3.0 \text{ V}$. As shown in Fig. 3(b), active current (50/90 log-normal statistic, 40 krad(Si) total dose) changed from 38.8 μA by 860 μA at $V_{cc} = 1.8 \text{ V}$ and from 156 μA by 1.17 mA at $V_{cc} = 3.0 \text{ V}$. Shifts in other electrical parameters were not significant.
B. Gamma Radiation

Regarding the Co\textsuperscript{60} (gamma) radiation testing, the unbiased test failure levels were about the same as the X-ray unbiased failure level.

1) The mean highest no-failure level was 36.9 krad(Si) with a sigma of 2.3. The log normal statistics place the 10-sample 50/90 point at 35.8 krad(Si) and the 99/90 point at 29.5 krad(Si).

2) Biased parts (5) failed at a somewhat lower total dose than with X-rays. Biased failures occurred at a mean of 27.84 krad(Si) with a sigma of 2.42. The log normal statistics place the 50/90 point at 26.0 krad(Si) and the 99/90 point at 18.0 krad(Si).

3) As shown in Fig. 3(a), for unbiased parts, standby current [50/90 log-normal statistic, 40 krad(Si) total dose] changed from 500 nA by 841 nA at $V_{cc} = 1.8$ V and from 7.7 $\mu$A by 7.17 $\mu$A at $V_{cc} = 3.0$ V. As shown in Fig. 3(b), active current (50/90 log-normal statistic) changed from 37.0 $\mu$A by 6.32 $\mu$A at $V_{cc} = 1.8$ V (30 krad(Si) total dose) and from 152 $\mu$A by 7.46 $\mu$A at $V_{cc} = 3.0$ V [40 krad(Si) total dose]. Shifts in other electrical parameters were not significant.

4) As shown in Fig. 4(a), for unbiased parts, standby current [50/90 log-normal statistic, 40 krad(Si) total dose] changed from 500 nA by 1.23 mA at $V_{cc} = 1.8$ V and from 7.6 $\mu$A by 1.67 mA at $V_{cc} = 3.0$ V. As shown in Fig. 4(b), active current (50/90 log-normal statistic)
changed from 37.2 $\mu$A by 969 $\mu$A at $V_{cc} = 1.8$ V [30 krad(Si) total dose] and from 152 $\mu$A by 1.18 mA at $V_{cc} = 3.0$ V [40 krad(Si) total dose]. Shifts in other electrical parameters were not significant.

As shown in Table II, the tests conducted on the AT24C64 EEPROM IC's suggest that their technology is less sensitive to ionizing radiation (gamma from Co^{60} source) than prior EEPROM technologies (READ mode).

V. DISCUSSION

To analyze the suitability of using an EEPROM within an implantable device, these test results must be translated to dosimetry units which can be related to diagnostic and therapeutic exposure of human patients:

A. Gamma Radiation

It must be remembered that for X-rays and gamma radiation, it can be assumed [10] that 1 roentgen (R) of exposure = 1 rad(mrem) of dose = 1 rem. For silicon oxide on the other hand, the exposure-to-dose conversion factor varies as a function of photon energy. 1.25 MeV mono energetic Co^{60} gamma radiation has been reported to be absorbed with a conversion factor of 0.88 rad(Si)/R. In general, deep-therapy X-rays and gamma rays from radium decay products possess a photon energy of 124 keV to 1.3 MeV, and within this range, the exposure-to-dose factor $f(rad(Si)/R) \approx 1$, and thus 1 rad(Si) $\approx$ 1 rad(mrem).

This implies that the unbiased AT24C64 EEPROM would directly withstand a Co^{60} total dose equivalent to approxi-
mately 30 krad(\text{man}) = 300 Gray(\text{man}). For the purpose of evaluating this dose level in the context of radiation therapy, one should consider that typical therapeutic X-ray (high-energy photons) or Co\textsuperscript{60} total doses deposited on a target tumor seldom exceed 60 Gray(\text{man}) \cite{11}. This dose is usually deposited over a number of sessions, and rotation or multiple beams are used to reduce the dose absorbed by healthy tissues, which would result in the implanted device absorbing only a small fraction of the dose deposited on the treated tissue. As such, even if high-energy X-rays or gamma radiation would be targeted directly at an unbiased EEPROM during a typical radiation treatment, the absorbed dose would still be five times lower than that required to cause failure. It must be remembered that this estimate does not account for the shielding and fluorescence of the implantable device's case.

The evaluated radiation-hardness for the unbiased AT24C64 (≈ 300 Gray(Si)) surpasses the overall radiation hardness reported for implantable pacemakers \cite{12, 13, 14, 15} against high-energy photons (Linac or Co\textsuperscript{60}). Operational failures have been reported for total doses as low as 10 Gray (complete failure of a CPI 505-102210) and up to 186 Gray (telemetry failure of an unidentified pacer using 3 \text{ \mu m } CMOS technology). In general, pacers based on the most modern technology reported (3 \text{ \mu m } CMOS) start to fail only after a total dose of 76 Gray. Although it is not clear from the presentations of any of these studies what material was used for dose calculations, a rough approximation can be made by assuming that for high-energy photons 1 rad(Si) ≈ 1 rad(\text{man}).

In any case, even without failure due to data corruption, parametric shifts in biased devices are sufficiently large that maintaining the EEPROM unbiased for most of the time would be recommendable. This is especially important for standby and operational currents, which may impose an intolerable drain on the implantable device's power supply after irradiation. Implantable cardiac pacemakers for example, typically derive their power from a relatively high-impedance battery (200 Ω\text{--}100 kΩ range as a function of discharge for typical Lithium-Iodide battery chemistry with deliverable capacities in the 1–1.7 Ah range) and impose on it an operating nominal current drain of approximately 20 \mu A. While a change in standby current for an EEPROM that is kept unbiased most of the time from 500 nA (at V\text{cc} = 1.8 V) by 841 nA [due to exposure to 40 krad(Si) Co\textsuperscript{60} gamma-rays] is well within tolerable limits, the 1.23 mA change caused by the same exposure for a biased part would result in a drastic and intolerable reduction of the pacemaker's battery remaining longevity.

B. X-Rays

X-rays in the range of interest (60–150 kVp) for diagnostics are absorbed differently than higher-energy X-rays and gamma radiation, and an estimate of absorption may be obtained as follows.

1) The exposure-to-dose conversion factor at any single spectral line is obtained from

\[ f(\text{rad(Si)}/\text{R}) = 0.869(\mu \varepsilon_{\text{Si}}/\rho_{\text{Si}})/(\mu \varepsilon_{\text{Au}}/\rho_{\text{Au}}) \]

where (\mu \varepsilon/\rho) is the mass energy absorption coefficient for a certain medium at a certain radiation wavelength.

2) The overall conversion coefficient could only be obtained by accounting for every portion of the X-ray spectrum, including the bremsstrahlung (stopping radiation, which produces a continuous spectrum) and characteristic radiation (sharp spectral lines corresponding to orbital transitions in the X-ray tube target). However, since X-ray energy production is highly dependent on the X-ray tube voltage throughout a powerline rectified cycle, it can be assumed that most of the X-ray photons will actually have an energy of about 1/3 to 1/2 the applied kVp. Table III can then be used to select the appropriate mass energy absorption coefficients.

As such, at 150 kVp most of the X-ray photons would be emitted in the 50–75 keV range. An estimate can then be obtained by using the mass energy absorption coefficients for 60 keV to yield \( f(\text{rad(Si)}/\text{R}) = 4.11 \). This means that for each rad that would be deposited in a human [rad(\text{man})], 4.11 rad would be deposited in silicon, and that the human-equivalent 150 kVp X-ray dose required to cause EEPROM data-pattern failure would be 26.8 krad(Si)/4.11 rad(Si)/rad(\text{man}) = 6.52 krad(\text{man}).

Considering that a typical chest X-ray results in a dose of approximately 0.025 rad(\text{man}), and that even an extremely lengthy fluoroscopy at implant would result in less than 5 rad(\text{man}), the diagnostic X-ray dose required to cause data failures in the AT24C64 EEPROM IC is many orders of
magnitude away from that which a patient would be exposed to.

VI. CONCLUSION

From the prior analysis of experimental data collected on the AT24C64 it is reasonable to conclude that selected floating-gate EEPROM technology can be considered safe and effective for use as a means for nonvolatile parameter and data storage for implantable medical devices when exposed to typical diagnostic or therapeutic photon irradiation.

Based on the analysis presented above, we provide the following technical recommendations for the use of EEPROM technology in implantable medical devices.

1) The application of the EEPROM shall minimize the number of E/W cycles to ensure maximum reliability of the device. In a recommended application, the EEPROM would be programmed once (or a very small number of times) during manufacturing, and then again at every follow-up when the implantable device’s parameters are reprogrammed by the attending physician. This would result in a very small number of E/W cycles over the lifetime of the device. However, if the EEPROM would be continuously used for storing automatically-logged data, its life would be reduced, possibly to unacceptable levels.

2) Data shall not be written into EEPROM at times other than a follow-up visit when the implantable device’s parameters are reprogrammed. Previous work has shown that floating-gate EEPROM’s are most vulnerable to ionizing radiation during E/W cycles. This recommendation would ensure that E/W cycles cannot occur while the device is exposed to large amounts of ionizing radiation. This would additionally ensure minimal failure of the EEPROM due to minimal stressing of the device.

3) If possible, the EEPROM shall be used only as “shadow” storage for volatile registers within the implantable medical device. In this way, the EEPROM can remain unbiased most of the time, with brief periods of activity limited to times when the contents of the volatile registers are to be verified or restored.

4) If sufficient storage space exists in the selected EEPROM IC, critical data (e.g., model and identification data, trims and calibrations, programmed parameters, etc.) shall be written redundantly. In addition, error-detection and error-correction schemes (e.g., cyclic redundancy checks) shall be implemented to ensure data validity.

5) Whenever radiation-hardness is desired for extremely harsh ionizing radiation environments, floating-gate EEPROM’s shall be substituted by a design based on SNOS transistors. Wellekens et al. [16] and McWhorter et al. [17], [18] reported that SNOS-based EEPROM’s are capable of withstanding in excess of 500 krad(Si) before failure.

6) Prudent safety measures must be observed when exposing patients to high levels of ionizing radiation. Currently, most if not all physician’s manuals for active implantable medical devices warn that therapeutic equipment that produces ionizing radiation can damage CMOS circuitry, with some companies specifying the total allowed cumulative dose [19]. Although a certain safety margin is included in these calculations, it is best that such labeling be maintained and observed.

It is expected that the results presented above will provide the data necessary for justifying the integration of nonvolatile memory technology within implantable medical devices, and that the protocols will serve as the basis for establishing comprehensive photon radiation-testing methodologies suitable for future designs. The importance of this information is rapidly increasing as the effects of medical diagnostic and therapeutic radiation are becoming an issue of concern to physicians who often encounter the need for radiotherapy in the growing population of patients implanted with pacemakers, defibrillators, neural stimulators, and drug-delivery pumps. As such, results from future tests under the specified reporting methods should enable the development of concise guidelines to aid physicians in effectively managing patients with active implantable medical devices.

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REFERENCES

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